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MEMORANDUM

SUBJECT: **TRIALATE.** HED Reregistration Eligibility Document.
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Attached is the **FINAL** HED RED chapter for triallate. A summary of the findings and an assessment of human risk are provided in the document. The hazard assessment was provided by Michelle Centra (Reregistration Branch III), the residue chemistry data and dietary risk assessment by José Morales (Reregistration Branch III), the occupational risk assessment by Seyed Tadayon (Chemistry and Exposure Branch I) and Julianna Cruz (Reregistration Branch III), and the water exposure by James Hetrick (EFED).

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1.0 EXECUTIVE SUMMARY

The Health Effects Division (HED) has conducted a human health risk assessment for the active ingredient **Triallate** [S-2,3,3-trichloroallyl diisopropylthiocarbamate] for the purpose of making a reregistration eligibility decision.

Triallate is a pre-emergent selective herbicide regionally registered for use on barley, lentils, peas (dried and succulent), triticale, and wheat. Triallate is sold in the United States by its basic producer, Monsanto Company, under the trade names Far-Go®, Buckle®, and Avadex BW ®. The 10% granular (G) and 4 lb/gal emulsifiable concentrate (EC) for Far-Go® and Buckle® are the only triallate formulations registered for food/feed uses. Depending on the crop, these formulations may be applied at application rates of 1.0-1.5 lb ai/A as preplant and postplant soil incorporated using ground or aerial equipment. Application is typically made either in the fall or in the spring before targeted weed species germinate. Regional registrations and tolerances (labels restrict the use to the following states: CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY) are currently established under 40 CFR §180.314 (a) for residues of parent triallate in or on the following commodities: barley grain and straw, 0.05 ppm (N); canary grass (annual) seed and straw, 0.05 ppm; lentils and lentil forage and hay, 0.05 ppm (N); peas and pea forage and hay, 0.05 ppm (N); wheat grain and straw, 0.05 ppm (N). No tolerances have been established for processed food/feed or animal commodities. At the request of the Special Review and Reregistration Division (SRRD), residue data for sugar beets are discussed in this chapter although sugar beets are not registered for use in the US. A tolerance petition for sugar beets is currently pending.

HED evaluated the toxicology, residue chemistry, and occupational exposure databases for triallate and determined that the data are adequate to support a reregistration eligibility decision. Acute and chronic dietary risk assessments were conducted as was a quantitative assessment of the potential exposure to triallate through drinking water. Since triallate is not used in a residential setting, an assessment of residential exposure was not conducted. As a result, the quantitative assessment of aggregate risk includes only dietary (food +water) exposure. HED also considered dermal and inhalation exposure to occupational handlers as well as to workers reentering treated fields.

Triallate is a herbicide in the class of thiocarbamates, which includes pebulate, molinate, EPTC, butylate, vernolate, and cycloate. As with other chemicals in this class, neurotoxicity is the major toxic effect of triallate; however, other toxic effects were also observed in the toxicology studies.

The triallate toxicity data base is considered complete to assess the potential hazard to humans, including special sensitivity of infants and children.

Triallate has a low order of acute toxicity via oral, dermal, or inhalation routes (Toxicity Category III or IV), produces slight irritation to the eyes and skin (Toxicity Category III or IV) and was shown to be a skin sensitizer in one assay and a non-sensitizer in another assay.

In subchronic studies in rats, the major toxicity appeared to be renal. In the 90-day subchronic feeding study in the rat, histopathology of the kidney (tubular epithelial regeneration and nephropathy) was observed in males at the 25 mg/kg/day dose level as well as decreased body weight in both sexes and slight anemia in females (decreased red blood cells, hematocrit and hemoglobin). Significant increases in the incidence of basophilic tubules of the renal cortex, alpha 2F-globulin inclusions in the proximal convoluted renal tubules were seen following subchronic oral and 21-day dermal exposures. Renal granular casts and incidence of hyaline droplet accumulation were also observed in the 90-day rat subchronic toxicity study. Additional toxicities observed following dermal exposures were increased relative kidney and liver weights and decreased body weight gain. In a 7 week inhalation toxicity study, histological changes in the kidney (nephropathy and tubular epithelial regeneration) occurred at concentrations of 0.01 mg/L (2.62 mg/kg/day).

Following chronic exposure, systemic toxicity in dogs was limited to an increase in liver weight in both sexes, increases in serum alkaline phosphatase in both sexes and increases in hemosiderin in the spleen at dose levels of 4.25 and 15 mg/kg/day. In mice, toxicities observed at the LOAEL of 60 ppm (9 mg/kg/day) included increased absolute liver weight, increased incidence of altered foci of the liver and hematopoiesis in the spleen. In rats, systemic toxicity manifested as decreased survival in both sexes, decreased body weight and increased adrenal weight in males at approximately 12.5 mg/kg/day. In high-dose males (12.5 mg/kg/day) from the chronic toxicity/carcinogenicity study, the only treatment-related finding at interim sacrifice was linear papillary mineralization in 1/10 rats (uncommon finding in rats at one year and typical of alpha 2F-globulin-induced renal pathology). The only treatment-related effect noted in male Syrian hamsters was decreased serum triglycerides at the mid- and high-dose levels of 300 ppm (LOAEL) and 2000 ppm.

There was no increased susceptibility to the offspring of rats following *in utero* exposure in the prenatal developmental toxicity study in rats, the two-generation reproduction study in rats, or the developmental neurotoxicity study in rats. However, there is evidence of increased susceptibility in the prenatal developmental toxicity study in rabbits. Maternal toxicity manifested as increased incidence of clinical signs and decreased body weight gain during the dosing period at 45 mg/kg/day (LOAEL); the NOAEL was 15 mg/kg/day. The LOAEL for developmental toxicity was 15 mg/kg/day based on decreased fetal body weight and increased incidence of malaligned sternebrae; the NOAEL was 5 mg/kg/day.

Triallate is neurotoxic in rats based on the acute neurotoxicity study, the subchronic neurotoxicity study, the rat multi-generation reproduction study and the developmental neurotoxicity study. Neurotoxic signs observed in these studies included gait abnormalities, increased alertness, waddling, rocking, lurching, circling movements, retropulsion, head shaking/bobbing and alterations in functional observation battery (FOB) and motor activity. In addition, triallate exposure resulted in

neuropathological lesions in both central and peripheral nerve fibers. However, triallate did not induce delayed neurotoxicity in hens.

Triallate induced genotoxic responses in several mutagenicity assays and is considered a mutagen. Positive responses occurred in the gene mutation assay in *Salmonella typhimurium*, in the mouse lymphoma forward mutation assay in L5178Y cells and in the sister chromatid exchange assay.

Triallate is classified as a Group C chemical (possible human carcinogen) based on hepatocellular carcinomas in male mice, with a positive trend and borderline significance in female mice and increased incidence of renal tubular cell adenomas in rats. A linear low-dose approach (Q_1^*) is used for human risk characterization. The unit risk, Q_1^* based on the hepatocellular carcinomas in male mice, is $7.17 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$ in human equivalents [converted from animals to humans by use of the $(\text{mg/kg/day})^{3/4}$ cross species scaling factor].

A FQPA Safety Factor is required for triallate because *quantitatively*, there was evidence of increased susceptibility in the prenatal developmental toxicity study in rabbits: developmental effects (decreased fetal body weight and increased incidence of malformed sternbrae) were observed in the absence of maternal toxicity. However, the FQPA safety factor was reduced to 3x because: (i) the toxicology data base is complete; (ii) increased sensitivity was only observed in one species (rabbit); (iii) there is no quantitative or qualitative indication of increased susceptibility in the prenatal developmental toxicity study in rats, the two-generation reproduction study in rats, or the developmental neurotoxicity study in rats; (iv) there was no evidence of abnormalities to the fetal nervous system in the developmental neurotoxicity study in rats; and (v) adequate data are available or conservative modeling assumptions are used to assess dietary food and drinking water exposure; there are currently no registered residential uses for triallate.

An acute reference dose (RfD) of 0.05 mg/kg/day was determined for the subpopulation group, females 13-50 years, based on the NOAEL of 5 mg/kg/day in the developmental toxicity study in rats and an uncertainty factor of 100 (10x for inter-species extrapolation and 10x for intra-species variation). The skeletal variation (malaligned sternbrae) observed in the fetuses is presumed to occur after a single exposure (dose) and therefore, this endpoint is appropriate for this risk assessment. The 3x FQPA Safety Factor is applied only to the population subgroup, females 13-50, for the determination of acute dietary risk because the effects occur during *in utero* exposure. Therefore, the **acute population adjusted dose (PAD) is 0.017 mg/kg/day for the subpopulation group females 13-50 only and includes the additional 3x FQPA safety factor.**

An acute reference dose (RfD) of 0.60 mg/kg/day was determined for the general population (including adult males, infants and children), based on the NOAEL of 60 mg/kg/day in the acute neurotoxicity study and an uncertainty factor of 100 (10x for inter-species extrapolation and 10x for intra-species variation). The endpoint, altered motor activity, was observed in both sexes 7 hours after treatment and is appropriate for this exposure/population subgroup. A FQPA safety factor was not applied for acute dietary risk assessment in the general population because the endpoint of concern

(altered motor activity) was not observed during *in utero* exposure. Therefore, the **acute PAD and the acute RfD for the general population are the same.**

A chronic RfD of 0.025 mg/kg/day was determined on the basis of the two-year chronic toxicity/carcinogenicity study in rats and an uncertainty factor of 100 (10x for inter-species extrapolation and 10x for intra-species variation). The NOAEL in this study was 2.5 mg/kg/day and the LOAEL was 12.5 mg/kg/day based on decreased survival in males and females, decreased body weights in males and increased adrenal weights in males. The FQPA safety factor was not applied for chronic dietary risk assessment because the NOAEL used in deriving the chronic dietary RfD is based on systemic toxicities which are unrelated to the increased susceptibility observed following *in utero* exposure and there is no evidence of increased susceptibility following long-term exposure (e.g., in the two-generation reproduction study). Therefore, the **chronic PAD and the chronic RfD are the same.**

For short- and intermediate-term dermal and inhalation exposure risk assessments, the developmental NOAEL of 5 mg/kg/day was selected. The dermal toxicity study was considered not appropriate for dermal risk assessments due to the lack of comparable toxicity via the oral and dermal route in the same species (rats) as well as the concern for the developmental effects seen and the occupational exposure for female workers. The inhalation toxicity study was not used since the study had a number of technical deficiencies. A Margin of Exposure of 100 is adequate for occupational exposure risk assessment. The FQPA safety factor is not applicable since triallate does not have registered residential uses at the present time.

Potential exposure to triallate occurs through food and water. The residue chemistry data are adequate to support reregistration. The HED Metabolism Assessment Review Committee (L. Cheng memo of 6/22/98) has determined that only triallate and its metabolite TCPSA (2,3,3-Trichloroprop-2-enesulfonic acid) should be regulated and assessed for dietary exposure in plant commodities. The HED Metabolism Committee concluded to regulate on the TCPSA metabolite because it is present at more than 10% of the TRR in the plant metabolism studies, and in the absence of toxicological data for this metabolite, the same toxicity as the parent compound was assumed.

In addition, the HED Metabolism Assessment Review Committee (L. Cheng memo of 6/22/98) has concluded that meat, egg and milk tolerances are not required, pending results of the rotational crop studies and reassessment of animal feed tolerances. No tolerances have been established for processed food/feed or animal commodities. No Codex MRLs have been established for residues of triallate. Adequate methods are available for the enforcement of triallate and TCPSA tolerances in/on plant commodities.

Dietary risk assessments reflected highly refined exposure assessments; anticipated residues and percent-crop-treated figures were incorporated. Refinements were conducted in anticipation of a cumulative risk assessment being conducted in the future (possibly on the thiocarbamates as a class). Refinements also permit a more realistic comparison of Drinking Water Levels of Comparison

(DWLOC) with estimates of potential drinking water concentrations provided by the Environmental Fate and Effects Division (EFED). Two probabilistic/Monte Carlo type of acute dietary assessments were conducted using an acute population adjusted dose (aPAD) of 0.017 mg/kg/day for females 13+ and an acute PAD of 0.60 mg/kg/day for infants, children, and the general population; **acute risks estimated at the 99.9th percentile of exposure to all population subgroups were <2% of the aPAD.** Chronic (non-cancer) risks were calculated using a chronic PAD (cPAD) of 0.025 mg/kg/day for the general population, infants, and children; **chronic dietary risks estimates to all population subgroups were <1% of the cPAD.** Chronic (cancer) dietary analysis indicates that the cancer dietary risk estimate of 7.1×10^{-8} for the general US population associated with the uses supported through reregistration and the proposed use on sugar beets of triallate is below the Agency's level of concern.

Since the triallate uses on spring and winter wheat are expected to yield the highest source loading of triallate in surface and ground waters, these crop scenarios were used to predict triallate concentrations in ground and surface waters. Using Tier II surface water models (PRZM-EXAMS) with the index reservoir (IR) and the percent crop correction factor (PCA), the Environmental Fate and Effects Division (EFED) predicts that chronic estimated environmental concentrations (EECs) for triallate residues (triallate + TCPSA) are 0.57 ppb (assuming 2" soil incorporation) and 1.26 ppb (assuming no incorporation) for spring triallate applications.

PRZM/EXAMS is a screening model that provides an upper-bound estimate of a pesticide's concentration in a 1 ha pond resulting from surface water runoff from a 10 ha field. PRZM/EXAMS is used to provide refined estimates of pesticide concentrations in the pond. Application rates, sites, and crop-specific scenarios can be modeled using PRZM/EXAMS. PRZM/EXAMS also uses NOAA climatological (rainfall) data for a 36-year period that allows for more realistic runoff events. PRZM/EXAMS can provide maximum and annual concentrations for each of the 36 years for which there is rainfall data.

Non-targeted surface water monitoring data from the USGS National Water Quality Assessment (NAWQA) program indicate that chronic concentrations of triallate in filtered surface waters from high use triallate areas are substantially lower than PRZM-EXAMS predictions. The maximum time-weighted annual mean concentration of triallate (parent only) in surface water is 0.077 ppb. Surface water data from Canadian monitoring studies on unfiltered surface waters suggest similar trends. There are no surface water monitoring data for TCPSA to assess runoff potential from actual triallate use.

Tier 1 modeling (SCI-GROW) for ground water indicates that the maximum triallate residue concentrations are not likely to exceed 0.21 ppb. Additionally, there have been no detections of triallate in ground water monitoring studies including NAWQA and STORET. Triallate also was not included in the EPA Pesticide in Ground Water Database (PGWDB). Environmental fate data for triallate suggest that triallate is not expected to move into groundwater because it has moderately high sorption affinity to soil (low mobility) and low to moderate persistence. In contrast, TCPSA has fate

properties of pesticides (low Koc and moderate persistence) found in groundwater. There are no ground water monitoring data for TCPSA to assess leaching potential under actual use conditions.

The acute DWLOCs for the US population, children (1-6) and females (13+ years) are 20,990 ppb, 6,000 ppb and 500 ppb, respectively. The chronic (non-cancer) DWLOCs for the US population, children (1-6) and females (13+ years) are 875 ppb, 250 ppb and 750 ppb, respectively. The cancer DWLOC is 0.45 ppb. Estimated maximum concentrations of triallate + TCPSA in surface water are 4.229 ppb (2" incorporation) and 9.452 ppb (no incorporation). The estimated average concentration of triallate (+ TCPSA) in surface water is 0.566 ppb (mean annual with 2" incorporation) and 1.257 ppb (mean annual with no incorporation). Concentrations in ground water are not expected to be higher than 0.21 ppb. Note: For the purposes of the screening-level assessment, the maximum and average concentrations in ground water are not believed to vary significantly. The maximum estimated concentrations of triallate +TCPSA in surface and ground water are less than OPP's DWLOCs for triallate +TCPSA in drinking water as a contribution to acute and chronic (non-cancer) aggregate exposure. **However, the 36 year annual mean estimated concentrations exceed OPP's DWLOC for triallate +TCPSA in drinking water as a contribution to cancer aggregate exposure.**

The drinking water exposure assessment, based on monitoring and modeling data, indicate that triallate (parent only) concentrations are below the cancer DWLOC. However, with no monitoring data available for the metabolite, TCPSA, and the surface water EECs of cumulative triallate residues exceeding the cancer DWLOC, HED cannot conclude with reasonable certainty that no harm will result from chronic (cancer) aggregate exposure to triallate and TCPSA residues.

Triallate can be applied with a groundboom, tractor- drawn spreader, or enclosed fixed- wing - aircraft, at a rate of 1.00 qt to 1.5 quarts active ingredient (a.i.) per acre for liquid and 1.25 to 1.5 pounds a.i. per acre for granules. Aircraft application is banned for BUCKLE[®], due to presence of %,%,%-trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine which is the other active ingredient in BUCKEL[®]. Aerial application of granular formulations is about 1 percent of total use. There has been relatively few incidents of illness reported due to triallate use. On the list of the top 200 chemicals for which the National Pesticide Telecommunications Network received calls from 1984-1991, triallate was not reported to be involved in human incidents.

Based on the handlers activity use pattern the duration of exposure is only short-term (1-7 days) and intermediate-term (1 week to 6 months) for occupational handlers. This is based on the fact that there are different planting periods of the registered crops for triallate. Based on the current use pattern (Maximum application rate of 1.5 lb (a.i.) /A per year) and handler activities, long-term (chronic) dermal exposure is not anticipated (nor expected); therefore, a dose and end point was not identified by HIARC nor is a long-term (chronic) exposure risk assessment required.

The Pesticide Handler Exposure Database (PHED) was used because there is no chemical specific data, which reflects the actual use patterns for this herbicide. When using PHED as a tool for

estimating exposure, high confidence data have a grade quality of A or B and a minimum of 15 replicates per body part. Low confidence data are based on D or E grade data and/or fewer than 15 replicates per body part. Mixing/loading and applying liquids for groundboom scenario(s) have **high quality** grade data. Mixing/loading liquids in support of enclosed fixed wing-aircraft have **high quality** grade data, and applying liquids for an enclosed fixed wing- aircraft scenario have **medium quality** grade data. Mixing/loading granulars in support of an enclosed fixed wing-aircraft, and tractor drawn broadcast spreader scenario(s) have **low quality grade data for dermal data points but has high quality data for inhalation data points**. Applying granulars for aerial and tractor drawn broadcast spreader scenario(s) have low quality grade data.

There is minimal potential for triallate exposure via inhalation because of the low acute toxicity ($LC_{50} > 5.3$ mg/L, Toxicity Category IV), low vapor pressure (16mPa at 25° C, for the technical grade) and low unit exposure values of daily inhalation doses at the baseline. However, occupational inhalation daily dose values were still calculated and presented for this risk assessment. **All calculated inhalation MOEs (short-, and intermediate-term) ranged between 330 to 8,400 which are greater than the target MOE of 100; which does not exceed HED's level of concern.**

For occupational handlers, dermal MOE(s) above 100 do not exceed HED's level of concern. All occupational exposure risk estimates, for Far-Go® (Granular and Liquid) formulation for short- and intermediate-term exposures for handlers, do not exceed HED's level of concern at baseline protection and for enclosed fixed wing-aircraft scenarios (calculated dermal MOEs for mixer/loaders are > 6,800, for applicators, and flaggers are > 5000), **except for scenarios; 1a** [Mixing/loading liquids for ground boom application (MOE=86)], **and 1b** [Mixing/loading liquids for aerial application (MOE=20)]; **however with additional PPE (gloves) for these two scenarios, exposure risk estimates, do not exceed HED's level of concern (MOEs are above 2500).**

Aggregate Occupational Handler Exposure Risks

For occupational handlers, MOE(s) above 100 do not exceed HED's level of concern. All occupational exposure aggregate (dermal+inhalation) risk estimates, for Far-Go® (Granular and Liquid) formulation for short- and intermediate-term exposures, **do not exceed HED's level of concern at the baseline protection and enclosed fixed wing-aircraft scenarios** [a range finding risk estimate was calculated, of the smallest aggregate daily dose (scenario 2a = {dermal + inhalation} = 1.574×10^{-2} mg/kg/day); which calculated a MOE = 320], **except for scenarios; 1a) and 1b); however with additional PPE (gloves) to minimize dermal exposures for these two scenarios, exposure risk estimates, do not exceed HED's level of concern** [a range finding risk estimate was also calculated, of the smallest aggregate daily dose (scenario 1b = {dermal + inhalation} = 1.25×10^{-2} mg/kg/day); which calculated a MOE = 400].

An assessment was conducted for the carcinogenic risk estimates associated with Triallate following exposures to occupational handlers (*private and commercial; mixers, loaders and applicators*). The cancer risks, for the handler (dermal plus inhalation) exposures, are based on the

assumption that a private farmer applies Triallate products, 15 times a year (Fall, Spring), and a commercial applicator applies Triallate products to 10 farms, 30 times a year (Fall, Spring). **Cancer risk estimates at baseline protection** (i.e., long-sleeve shirt, long pants, no gloves, shoes, and socks) and enclosed fixed wing-aircraft scenarios **do not exceed 4.0×10^{-5} , except for (1a)**[mixing/loading liquids] in support of groundboom, **(1b)** [mixing/loading liquids], **and (2a)** [loading granules] in support of aerial application; **however, with implementing risk mitigation [additional PPE; gloves] to minimize dermal exposures cancer risk estimates do not exceed 3.8×10^{-5} .** With the **implementation of engineering controls, cancer risks estimates do not exceed 7.78×10^{-6} .**

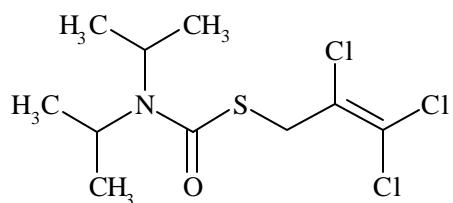
*Exposure assessment risk estimates were only conducted for enclosed fixed wing-aircraft, see section 4.3.1, Handler Exposures and Assumptions for rationale. **Therefore a restriction should be put on the label, that only allow for enclosed fixed wing-aircraft applications.***

No DFR (Dislodgeable Foliar Residue) data or exposure monitoring data were submitted for Triallate. However, HED believes that the potential for post-application worker exposure is low, provided the 12 hour restricted entry interval is observed. **There is low potential for exposure** due to the timing of applications. Triallate is applied to the soil and/or soil incorporated pre-emergence for wheat, barley, peas, and lentils. This is well before the plants are mature, which likely mitigates the potential for post-application exposure due to contact with treated foliage. Additionally, most agricultural operations for wheat, barley, peas, and lentils are mechanically harvested which minimizes the potential for contact. **Significant exposure to Triallate during mechanical planting, harvesting, or any other late season activities, is not likely** since Triallate is applied pre-emergent (per Exposure Scientific Advisory Committee (SAC) policy #8). Also significant exposure to Triallate during scouting, or while handling or coming in contact with treated soil is minimum (less than or equal to the amount of exposure that occurs in the application of triallate; which did not exceed HED's level of concern), and would not exceed HED's level of concern. **Therefore, HED does not require that any Post-application exposure data be generated to support the reregistration of Triallate.**

There are no residential uses nor are there any occupational uses resulting in non-dietary exposure to infants and children, at this time.

2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION

2.1 Structural Formula



Empirical Formula:	C ₁₀ H ₁₆ Cl ₃ NOS
Molecular Weight:	304.66
CAS Registry No.:	2303-17-5
PC Code:	078802

2.2 Identification of Active Ingredients

Triallate technical is an amber to dark brown solid with a melting point of 29-30 EC, specific gravity of 1.2600-1.2624 at 35 EC, octanol/water partition coefficient (log K_{ow}) of 4.54, and vapor pressure of 1.1 x 10⁻⁴ mm Hg at 25 EC. Triallate is slightly soluble in water (4 ppm at 25 EC), and is soluble in methylene chloride, n-octanol, and toluene at >200 g/100 mL.

3.0 HAZARD CHARACTERIZATION

3.1 Hazard Assessment

The triallate toxicity data base is considered complete to assess the potential hazard to humans, including special sensitivity of infants and children.

Triallate has a low order of acute toxicity via oral, dermal, or inhalation routes (Toxicity Category III or IV) and produced slight irritation to the eyes (Toxicity Category III) and skin (Toxicity Category IV). Triallate was not a skin sensitizer in the Buehler dermal sensitization assay but was shown to be a sensitizer in the guinea pig maximization sensitization assay.

In subchronic studies in rats, the major toxicity appeared to be renal. In the 90-day subchronic feeding study in the rat, histopathology of the kidney (tubular epithelial regeneration and nephropathy) was observed in males at the 25 mg/kg/day dose level as well as decreased body weight in both sexes and slight anemia in females (decreased red blood cells, hematocrit and hemoglobin). Following oral

exposures, immunohistochemical staining showed increased intensity of alpha 2F-globulin staining in treated male rats, although the total incidence of animals with positive staining did not show a clear increase. In the high dose males from the subchronic study, the incidence and severity of chronic progressive nephropathy was increased at 2000 ppm. Granular casts and incidence of hyaline droplet accumulation were also observed.

Following dermal exposures, significant increases in the incidence of basophilic tubules of the renal cortex and alphaF-globulin inclusions in the proximal convoluted renal tubules were seen. Also observed were relative liver and kidney weight and decreased body weight gain. In a 7 week inhalation toxicity study, histological changes in the kidney (nephropathy and tubular epithelial regeneration) occurred at a concentration of 0.01 mg/L (2.62 mg/kg/day).

Following chronic exposure, systemic toxicity in dogs was limited to an increase in liver weight in both sexes, increases in serum alkaline phosphatase in both sexes and increases in hemosiderin in the spleen at dose levels of 4.25 and 15 mg/kg/day. In mice, toxicities observed at the LOAEL of 60 ppm (9 mg/kg/day) included increased absolute liver weight, increased incidence of altered foci of the liver and hematopoiesis in the spleen. In rats, systemic toxicity manifested as decreased survival in both sexes, decreased body weight and increased adrenal weight in males at approximately 12.5 mg/kg/day. In high-dose males from the chronic toxicity/carcinogenicity study, the only treatment-related finding at interim sacrifice was linear papillary mineralization in 1/10 rats (uncommon finding in rats at one year and typical of alpha 2F-globulin-induced renal pathology). The only treatment-related effect noted in male Syrian hamsters was decreased serum triglycerides at the mid- and high-dose levels of 300 ppm (LOAEL) and 2000 ppm.

In accordance with the Agency's Proposed Guideline for Carcinogen Risk Assessment (April 11, 1993), the HED Cancer Peer Review Committee classified triallate as a Group C chemical - possible human carcinogen. This classification is based on the following factors: (i) hepatocellular carcinomas found in male mice at minimally adequate doses, with a positive trend and a borderline significant increase in females at inadequate doses, (ii) the increased incidence in male rats of renal tubular cell adenoma (a rare tumor type) above historical control levels was considered biologically significant, although no absolute pair-wise statistical significance was found, (iii) triallate is considered a mutagen because of positive genotoxicity results in *Salmonella typhimurium*, mouse lymphoma cells and Chinese hamster cells and (iv) triallate is structurally related to several carcinogenic analogs such as sulfallate, telone II and dichlorvos. (Memorandum: J. Rowland, 1/12/94).

The Cancer Peer Review Committee (CPRC) has requested that a new carcinogenicity study be repeated using female B6C3F1 mice only because the dosing was judged to be inadequate (the results of this study are considered critical to the ultimate cancer classification of triallate). If the registrant chooses not to repeat this study and in the absence of any additional relevant data, the existing low-dose extrapolation model (Q_1^*) based on the induction of liver tumors in the male mouse will continue to be used in risk assessment (CPRC Memorandum; J. Rowland, 1/12/94).

The CPRC recommended that the human risk characterization and extrapolation of risk should be based on the occurrence of hepatocellular carcinomas in male mice at minimally adequate doses. The unit risk, $Q_1^* \text{ (mg/kg/day)}^{-1}$ for triallate, based on the occurrence of hepatocellular carcinomas in male mice, is $7.17 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$ in human equivalents [converted from animals to humans by use of the $\text{(mg/kg/day)}^{3/4}$ cross species scaling factor - Tox_Risk program, version 3.5, K. Crump, 1994]. (Memorandum, Lori Brunsman, 10/28/98).

There was no increased susceptibility to the offspring of rats following *in utero* exposure in the prenatal developmental toxicity study in rats, the two-generation reproduction study in rats, or the developmental neurotoxicity study in rats. In the rat developmental toxicity study, the dams were more sensitive than the pups; the maternal toxicity NOAEL was 10 mg/kg/day and the LOAEL was 30 mg/kg/day based on decreases in body weight and food consumption whereas the developmental toxicity NOAEL was 30 mg/kg/day and the LOAEL was 90 mg/kg/day based on decreased fetal weight, external malformations and skeletal variations. Increased neonatal mortality during the F_{2b} litter interval, reduced pup weights at birth during the F_{2b} litter interval, reduced pup weights in late lactation for all litters, reduced pregnancy rate and shortened gestation length occurred at the same dose (30 mg/kg/day) which produced maternal toxicity (increased mortality, increased incidences of chronic nephritis, head bobbing, circling movements and reduced body weights) in the two-generation reproduction study; the maternal and offspring toxicity NOAELs were 7.5 mg/kg/day. Similarly, offspring toxicity occurred at the same dose which produced maternal toxicity in the developmental neurotoxicity study. For maternal toxicity, the NOAEL was 30 mg/kg/day and the LOAEL was 60 mg/kg/day based on reductions in body weight gains and food consumption. At 60 mg/kg/day (developmental neurotoxicity LOAEL), there were several parameters affected in the developing offspring; reductions in body weight in both sexes, increased motor activity in both sexes and decreases in passive avoidance latency in females. The developmental neurotoxicity NOAEL was 30 mg/kg/day.

However, there is evidence of increased susceptibility in the prenatal developmental toxicity study in rabbits since the developmental effects were observed at a dose lower than the dose which produced maternal toxicity. Maternal toxicity manifested as increased incidence of clinical signs and decreased body weight gain during the dosing period at 45 mg/kg/day (LOAEL); the NOAEL was 15 mg/kg/day. The LOAEL for developmental toxicity was 15 mg/kg/day based on decreased fetal body weight and increased incidence of malaligned sternebrae; the NOAEL was 5 mg/kg/day.

Triallate did not produce neuropathology in hens at doses up to 312.5 mg/kg in the acute delayed neurotoxicity study. However, there is evidence that triallate is neurotoxic in rats based on the following studies. In the acute neurotoxicity screening study, neurotoxic signs include gait abnormalities, increased alertness, waddling, rocking, lurching, circling movements, retropulsion, and head shaking, decreases followed by increases in motor activity and other symptoms at 300 or 600 mg/kg. The rat subchronic neurotoxicity study indicated pathological lesions in the nerve fibers of both central and peripheral origin, FOB changes and increased motor activity at dose levels of approximately 33 mg/kg/day and above. In addition, head bobbing and circling movements were noted in the rat multi-generation reproduction study in the parental groups at 600 ppm (30 mg/kg/day). A special

supplementary neurotoxicity study indicated that both central and peripheral neuropathological lesions result from triallate exposure at a dose level of 6000 ppm (295 mg/kg/day). The developmental neurotoxicity study indicated the fetuses exposed *in utero* and during lactation displayed increased motor activity at a maternal dose of 60 mg/kg/day but there was no associated neuropathology.

Triallate induced positive responses in both the presence and absence of S9 metabolic activation in the gene mutation in *Salmonella typhimurium* assay, in a mouse lymphoma forward mutation assay in L5178Y cells and in the sister chromatid exchange assay. There was, however, no evidence of a positive effect in a second mouse lymphoma forward mutation assay in L5178Y cells. Triallate was non-mutagenic in *in vivo* cytogenetic micronucleus assays in hamsters and mice or in two unscheduled DNA synthesis assays in primary rat hepatocytes.

Analysis of whole body elimination in male and female rats indicated that 85% of the radiolabeled triallate was excreted within 24 hours of dosing. Most radioactivity was excreted in approximately equal amounts (42%) in the urine and feces of male rats after 10 days. Females excreted 51% in urine and 32% in feces after 10 days. Males and females retained about 0.4% of the dose in organs and tissues and approximately 2.0% in the remaining carcass. The distribution of radioactivity in both sexes indicated that the greatest amount of activity was found in the red blood cells followed by whole blood, and spleen, kidney, liver and lung. Seven metabolites, in concentrations of greater than one percent, were identified in rat urine: 2,3,3-trichloro-2-propenesulfinic acid (20-27%), N-acetyl-S-(2,2-dichloro-1-[methyl-sulfonyl] methyl)ethenyl)-L-cysteine (6-11%), (E)-S-(2 carboxy-2-chloroethenyl)-L-cysteine (4-5%), carbon dioxide (4%), 2,3,3-trichloro-2-propene sulfonic acid; TCPSA (3-5%), (E)-3-((carboxymethyl)thio)-2-chloro-2-propenoic acid (1-3%), and 1-((3, 3, 2-trichloro-2-propenyl)thio)-beta-D-glucuronic acid. The remaining metabolites were found at less than 1% of the administered dose.

A dermal absorption study is not available in the database. The Hazard Identification Assessment Review Committee (HIARC) estimated a dermal absorption factor of 1% based on the ratio of the LOAEL of 30 mg/kg/day in the oral developmental toxicity study rats and the LOAEL of 3000 mg/kg/day in the 21 day dermal toxicity study in rats based on a common endpoint (decreased body weight gain). $[30 \div 3000 = 1\%]$

Tables 1 and 2 present the toxicity profiles for triallate.

TABLE 1. Acute Toxicity Profile for Triallate (Technical)				
Guideline	Study Type (Date)	MRID	Results	Tox. Cat.
870.1100 (§ 81-1)	Acute Oral-Rat (6/29/98)	4466070 1	LD ₅₀ (males) = 3612 mg/kg (2657-4909 mg/kg) LD ₅₀ (females) = 3455 mg/kg (2590-4611 mg/kg) LD ₅₀ (combined) = 3382 mg/kg (2755-4151 mg/kg)	III
870.1200 (§ 81-2)	Acute Dermal-Rabbit (1/11/91)	4219200 1	LD ₅₀ > 5000 mg/kg	IV
870.1300 (§ 81-3)	Acute Inhalation-Rat (9/9/82)	0012185 6	LC ₅₀ > 5.3 mg/L	IV
870.2400 (§ 81-4)	Primary Eye Irritation-Rabbit (1/22/98)	4459180 1	Slight eye irritant	III
870.2500 (§ 81-5)	Primary Dermal Irritation-Rabbit (1/27/98)	4458160 1	Slight dermal irritant	IV
870.2600 (§ 81-6)	Dermal Sensitization-Guinea pig Buehler test (10/7/83)	0013287 9	Non sensitizer	N/A
870.2600 (§ 81-6)	Dermal Sensitization-Guinea pig maximization test (6/6/97)	4430830 1	Dermal sensitizer	N/A
870.6100 (§ 81-7)	Acute Delayed Neurotoxicity-Hen (8/10/83)	0013287 4 4007210 4	Systemic NOAEL=312.5 mg/kg (not established) Systemic LOAEL=312.5 mg/kg based on acute, reversible clinical signs (muscle weakness/paralysis, salivation and involuntary neck movement) Triallate did not induce delayed peripheral neuropathy	N/A

TABLE 2. Subchronic and Chronic Toxicity Profile for Triallate				
Guideline	Study Type (Date)	MRID	Results	
Subchronic Toxicity				
870.3100 (§ 82-1)	90-Day Feeding- Rat (8/23/82)	0011563 9	Systemic NOAEL=100 ppm (5/mg/kg/day) Systemic LOAEL=500 ppm (25 mg/kg/day) based on decreased body weight in males and females, slight anemia in females (decreased red blood cells, hematocrit and hemoglobin) and histopathology of the kidney in males (tubular epithelial regeneration and nephropathy)	

TABLE 2. Subchronic and Chronic Toxicity Profile for Triallate			
Guideline	Study Type (Date)	MRID	Results
870.3200 (§ 82-2)	21-Day Dermal-Rat (1/29/90)	4148700 1	Systemic NOAEL = 500 mg/kg/day Systemic LOAEL = 3000 mg/kg/day based on body weight gain decreases, relative kidney and liver weight increases, increased presence of basophilic tubules of the renal cortex, and alphaF-globulin inclusions in the proximal convoluted renal tubules. Dermal NOAEL=100 mg/kg/day Dermal LOAEL=100 mg/kg/day based on increased incidences of acanthotic epidermal thickening.
(§ 82-2)	Subchronic Inhalation (6 hr/day 5 days/week for 7 weeks)-Rat (9/27/83)	4007210 5 0013287 8	NOAEL < 0.01 mg/L (2.62 mg/kg/day) not established LOAEL=0.01 mg/L (2.62 mg/kg/day) based on histological changes in the kidney (nephropathy and tubular epithelial regeneration).
Chronic Toxicity/Carcinogenicity			
870.4100 (§ 83-1)	Chronic Toxicity- Dogs (10/2/79)	0002945 5	Systemic NOAEL=1.5 mg/kg/day (1.27 mg/kg/day calculated) Systemic LOAEL=5.0 mg/kg/day (4.25 mg/kg/day calculated) based on increased hemosiderin deposition in the spleen, increased serum alkaline phosphatase and increased liver weight in females.
870.4100 (§ 83-1)	Chronic Toxicity- Dogs (2/4/88)	4073060 4	Systemic NOAEL=2.5 mg/kg/day Systemic LOAEL=15.0 mg/kg/day based on increased alkaline phosphatase levels at all time intervals in male and female dogs.
870.4200 (§ 83-2)	Chronic Toxicity/ Carcinogenicity -Rat (7/10/87)	4038470 1 4111690 1	NOAEL= 50 ppm (2.5 mg/kg/day). LOAEL= 250 ppm (12.5 mg/kg/day) based on decreased survival (males and females), decreased body weight (males) and increased adrenal weight (males). Evidence of carcinogenicity: Renal tubular adenomas in male rats.
870.4200 (§ 83-2)	Chronic Toxicity/ Carcinogenicity -Mice (10/83)	0013285 9	NOAEL(males) = 20 ppm (3 mg/kg/day) LOAEL(males) = 60 ppm (9 mg/kg/day) based on increased absolute liver weight, increased incidence of altered foci of the liver and hematopoiesis in the spleen. NOAEL(females) = 250 ppm (37.5 mg/kg/day) LOAEL(females) >250 ppm (37.5 mg/kg/day) not established Evidence of carcinogenicity: Increased incidence of hepatocellular carcinomas and hepatocellular adenomas (males).

TABLE 2. Subchronic and Chronic Toxicity Profile for Triallate			
Guideline	Study Type (Date)	MRID	Results
870.4200 (§ 83-2)	Chronic Toxicity/ Carcinogenicity- Hamster (10/18/84)	0015179 0 0015979 7	NOAEL=50 ppm LOAEL=300 ppm based on decreased triglyceride levels (males and females). No evidence of carcinogenicity
Developmental/Reproductive Toxicity			
870.3700 (§ 83-3)	Developmental Toxicity-Rat (5/10/82)	0011426 0 4170690 6	Maternal NOAEL = 10 mg/kg/day Maternal LOAEL = 30 mg/kg/day based on decreases in body weight gain and food consumption. Developmental NOAEL = 30 mg/kg/day Developmental LOAEL = 90 mg/kg/day based on decreased fetal body weight, external malformations (protruding tongue) and skeletal variations.
870.3700 (§ 83-3)	Developmental Toxicity- Rabbit (1/21/82)	0011426 1 4331500 1	Maternal NOAEL = 15 mg/kg/day Maternal LOAEL = 45 mg/kg/day based on clinical signs and decreases in body weight gain. Developmental NOAEL = 5 mg/kg/day Developmental LOAEL = 15 mg/kg/day based on decreased fetal body weight and increased skeletal variations.
870.3800 (§ 83-4)	2-Generation Reproduction Study-Rat (10/20/83, 7/11/84)	0014430 8 0013288 0	Parental/Systemic NOAEL = 150 ppm (7.5 mg/kg/day) Parental/Systemic LOAEL = 600 ppm (30 mg/kg/day) based on maternal mortality, increased incidences of chronic nephritis, head bobbing, circling movements and reduced body weights. Reproductive/Developmental NOAEL = 150 ppm (7.5 mg/kg/day). Reproductive/Developmental LOAEL = 600 ppm (30 mg/kg/day) based on increased neonatal mortality during the F _{2b} litter interval, reduced pup weights at birth during the F _{2b} litter interval, reduced pup weights in late lactation for all litters, reduced pregnancy rate and shortened gestation length.

TABLE 2. Subchronic and Chronic Toxicity Profile for Triallate			
Guideline	Study Type (Date)	MRID	Results
Mutagenicity			
870.5100 (\$84-2)	Gene Mutation in <i>Salmonella typhimurium</i> (7/1/77)	0008862 4	Positive. Triallate induced a mutagenic response in <i>Salmonella typhimurium</i> strains TA1535 and TA100 at noncytotoxic doses of 0.1 Fg/plate and above -S9 activation and TA1535, TA98 and TA100 at 0.001 Fg/plate and above +S9. In tester strains TA1537 and TA1538, there were no appreciable increases in revertant colonies or evidence of cytotoxicity at any dose. Mutagenesis was confirmed in a repeat test with <i>Salmonella typhimurium</i> strain TA1535 at dose levels of 1, 5, and 10 Fg/plate +/- S9 activation.
870.5300 (\$84-2)	Gene Mutation/ <i>In vitro</i> mammalian cell assay in mouse lymphoma cells (8/1/77)	0008364 4	Negative. Triallate did not induce forward gene mutations at the thymidine kinase (TK ⁺) locus in L51784 mouse lymphoma cells at concentrations of 0.005 to 0.04 Fl/mL in the absence or presence of metabolic activation.
870.5300 (\$84-2)	Gene Mutation/ <i>In vitro</i> mammalian cell assay in mouse lymphoma cells (8/1/77)	4109100 7	Positive. Triallate induced forward gene mutations at the thymidine kinase (TK ⁺) locus in L51784 mouse lymphoma cells. The frequency of gene mutations was greater than or equal to a two-fold increase and occurred at noncytotoxic concentrations of 60 Fg/mL -S9 activation and 21 and 24 Fg/mL+S9 activation.
870.5385 (\$84-2)	Cytogenetics/ <i>In vivo</i> hamster micronucleus assay (5/7/82)	0011426 3	Negative. There was no evidence of either a clastogenic or aneugenic effect in male and female hamsters fed dietary concentrations of 0, 600, 2000 or 6000 ppm Triallate at any sacrifice time.
870.5395 (\$84-2)	Cytogenetics/ <i>In vivo</i> mouse micronucleus assay (1/15/91, 10/15/97; Amendment)	4459170 1	Negative. There was no evidence of either a clastogenic or aneugenic effect in male and female mice administered 70, 350, or 700 mg/kg Triallate at any sacrifice time.
870.5550 (\$84-2)	Other Mutagenic Mechanisms/ <i>In vitro</i> unscheduled DNA synthesis in primary rat hepatocytes (11/14/85)	4073060 1	Negative. Triallate did not induce a genotoxic effect in primary rat hepatocytes at concentrations of 5, 10, 50, 100, 500 and 1000 Fg/mL.
870.5550 (\$84-2)	Other Mutagenic Mechanisms/ <i>In vivo/In vitro</i> unscheduled DNA synthesis in primary rat hepatocytes (9/20/89, 9/25/89; Amendment)	4470100 1	Negative. There was no evidence that Triallate induced either a cytotoxic or genotoxic response at any dose (50, 250 or 500 mg/kg) or sacrifice time (92 or 16 hours).

TABLE 2. Subchronic and Chronic Toxicity Profile for Triallate			
Guideline	Study Type (Date)	MRID	Results
870.5900 (\$84-2)	Other Mutagenic Mechanisms/ <i>In vitro</i> sister chromatid exchange in Chinese hamster ovary cells (9/3/82)	0012185 9	Positive. Triallate induced significant increases in the number of sister chromatid exchanges per cell at concentrations of 1.6×10^{-5} M to 8.1×10^{-5} M -S9 activation and 0.8×10^{-5} M to 4.0×10^{-5} M +S9 activation after either a two or four hour exposure period, respectively. Repeat assays conducted for 30 hours at concentrations up to 40.4×10^{-5} M -S9 activation and for 2 hours at concentrations up to 12.1×10^{-5} M +S9 activation confirmed these findings.

TABLE 2. Subchronic and Chronic Toxicity Profile for Triallate			
Guideline	Study Type (Date)	MRID	Results
Neurotoxicity			
870.6200 (§ 81-8)	Acute Neurotoxicity-Rat (7/8/93)	4290810 1	Systemic NOAEL=60 mg/kg Systemic LOAEL=300 mg/kg based on decreased body weight gain and alterations in motor activity
870.6200 (§ 82-7)	Subchronic Neurotoxicity-Rat (11/17/93)	4302160 1	Systemic/Neurotoxicity NOAEL=100 ppm (6.38/8.14 mg/kg/day for males/females) Systemic/Neurotoxicity LOAEL=500 ppm (32.9/38.9 mg/kg/day for males/females) based on decreased body, body weight gains , food consumption and lesions (nerve fiber degeneration) in the central and peripheral nervous systems.

TABLE 2. Subchronic and Chronic Toxicity Profile for Triallate			
Guideline	Study Type (Date)	MRID	Results
870.6200 (§ 82-7)	Subchronic Neurotoxicity-Rat (11/3/98)	4469450 1	<p>Neurotoxic NOAEL= 2000 ppm (achieved dose 134.32 mg/kg/day)</p> <p>Neurotoxic LOAEL = 4000 ppm (achieved dose 223.79 mg/kg/day) based on behavioral effects (histopathology for axonal degeneration was not conducted at this dose level)</p> <p>At 6000 ppm (295 mg/kg/day) neurohistopathological lesions in both the central and peripheral nerves.</p> <p>Systemic NOAEL = 500 ppm (34.64 mg/kg/day)</p> <p>Systemic LOAEL = 2000 ppm (achieved dose 134.32 mg/kg/day) was based on decreased body weight and food consumption and food efficiency.</p>

TABLE 2. Subchronic and Chronic Toxicity Profile for Triallate			
Guideline	Study Type (Date)	MRID	Results
870.6300 (§ 83-6)	Developmental Neurotoxicity-Rat (12/2/98)	4471050 1	Maternal NOAEL = 30 mg/kg/day Maternal LOAEL = 60 mg/kg/day based on reductions in body weight gains and food consumption Developmental Neurotoxicity NOAEL = 30 mg/kg/day Developmental Neurotoxicity LOAEL = 60 mg/kg/day based on increased motor activity.
Metabolism			
870.7485 (§ 85-1)	General Metabolism-Rat (10/6/83, Part I)	0013815 9	Analysis of whole body elimination in male and female rats indicated that 85% of the radiolabeled triallate was excreted within 24 hours of dosing. Most radioactivity was excreted in approximately equal amounts (42%) in the urine and feces of male rats after 10 days. Females excreted 51% in urine and 32% in feces after 10 days. Males and females retained about 0.4% of the dose in organs and tissues and approximately 2.0% in the remaining carcass. The distribution of radioactivity in both sexes indicated that the greatest amount of activity was found in the red blood cells followed by whole blood, spleen, kidney, liver and lung.
870.7485 (§ 85-1)	General Metabolism-Rat (8/83, Part II)	4007210 6	Seven metabolites, in concentrations of greater than one percent, were identified in rat urine: 2,3,3- trichloro-2-propenesulfinic acid (20-27%), N-acetyl- S-(2,2-dichloro-1-[methyl-sulfonyl] methyl)ethenyl)-L- cysteine (6-11%), (E)-S-(2 carboxy-2-chloroethenyl)- L-cysteine (4-5%), carbon dioxide (4%), 2,3,3- trichloro-propene sulfonic acid (3-5%), (E)-3- ((carboxymethyl)thio)-2-chloro-2-propenoic acid (1- 3%), and 1-((3, 3, 2-trichloro-2-propenyl)thio)-beta-D- glucuronic acid. The remaining metabolites were found at less than 1% of the administered dose.
Special Studies			
None	Assessment of the kidney for alpha 2F globulins in the rat subchronic and chronic feeding studies. (11/3/98)	4476750 1	Data from this study is considered a preliminary indication that triallate <i>may</i> be classified as an alpha 2F globulin type nephrotoxin. Additional data and analysis considered necessary for a more conclusive decision.

3.2. FQPA Assessment

Triallate was reviewed by the FQPA Safety Factor Committee and it was recommended that the FQPA 10 x factor be reduced to 3x based on the rationale provided below (Memorandum: B. Tarplee, 5/17/99).

The FQPA SFC concluded that a safety factor is required for triallate because *quantitatively*, **there was evidence of increased susceptibility** in the prenatal developmental toxicity study in rabbits:

- < developmental effects (decreased fetal body weight and increased incidence of malformed sternebrae) were observed in the absence of maternal toxicity.

The Committee recommended that the **FQPA safety factor** be **reduced** to 3x because:

- < the toxicology data base is complete;
- < increased sensitivity was only observed in one species (rabbit);
- < there is no quantitative or qualitative indication of increased susceptibility in the prenatal developmental toxicity study in rats, the two-generation reproduction study in rats, or the developmental neurotoxicity study in rats;
- < there was no evidence of abnormalities to the fetal nervous system in the developmental neurotoxicity study in rats;
- < adequate data are available or conservative modeling assumptions are used to assess dietary food and drinking water exposure; there are currently no registered residential uses for triallate.

The FQPA safety factor for triallate is **only applicable to the females 13 -50** population subgroup because the effects of concern (observed in the prenatal developmental toxicity study in rabbits) occur *in utero* and not during post-natal exposure.

The FQPA safety factor for triallate is **only applicable to acute dietary risk assessment** since the effects of concern were observed only during *in utero* exposure.

The NOAEL used in deriving the chronic dietary RfD is at a lower level than those used to derive the acute RfDs and is based on systemic toxicity observed in the combined chronic toxicity/carcinogenicity rat study. The systemic toxicity is unrelated to the increased susceptibility observed following *in utero* exposure. There is no evidence of increased susceptibility following long-term exposure (e.g., in the two-generation reproduction study).

3.3. Dose Response Assessment

The doses and toxicological endpoints selected and margins of exposure (MOEs) for various exposure scenarios are summarized in Table 3.

TABLE 3. SUMMARY OF TOXICOLOGY ENDPOINT SELECTION FOR TRIALLATE		
EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT/STUDY/RATIONALE
Acute Dietary (Females 13+)	NOAEL=5	Increased skeletal malformations/variations in the rabbit developmental toxicity study. The skeletal malformations are presumed to occur after a single exposure (dose) and thus are appropriate for this (acute) risk assessment. In addition, skeletal malformations (malaligned sternbrae) were also seen in rat fetuses following <i>in utero</i> exposure to triallate.
	UF=100 FQPA SF=3	
	Acute RfD = 0.05 mg/kg/day Acute PAD=0.017 mg/kg/day	
Acute Dietary (General Population)	NOAEL=60	Altered motor activity and changes in FOB in the rat acute neurotoxicity study. Because of the neurotoxic characteristics of triallate (altered motor activity observed in both sexes 7 hours after treatment at the mid- and high- doses that persisted up to 14 days in high-dose females), this endpoint is considered adequate for assessing risk in the general population.
	UF=100 FQPA SF=1	
	Acute RfD=0.60 mg/kg Acute PAD=0.60 mg/kg/day	

TABLE 3. SUMMARY OF TOXICOLOGY ENDPOINT SELECTION FOR TRIALLATE		
EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT/STUDY/RATIONALE
Chronic (non cancer) Dietary	NOAEL=2.5	Decreased survival in males and females, decreased mean body weights in males and increased adrenal weights in males in the 2-year chronic toxicity/carcinogenicity in rats. The HIARC re-assessed the RFD and determined that there is limited confidence in the toxicities observed in the 2-year chronic toxicity study in dogs previously used to establish this value. The committee has greater confidence in the toxicities observed in the 2-year chronic toxicity/carcinogenicity study in rats and therefore, the dose and endpoint were selected from this study.
	UF= 100 FQPA SF=1	
	Chronic RfD = 0.025 mg/kg/day Chronic PAD=0.025 mg/kg/day	
Chronic (cancer) Dietary	Group C chemical - “Likely to be a human carcinogen” - $Q_1^* = 7.17 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$ in human equivalents [converted from animals to humans by use of the $(\text{mg/kg body weight})^{3/4}$ cross species scaling factor].	
Dermal Absorption	A dermal absorption factor of 1% was estimated based on the ratio of the LOAEL of 30 mg/kg/day in the oral developmental toxicity study and the LOAEL of 3000 mg/kg/day in the 21 day dermal toxicity study in rats.	
Short- and Intermediate-Term (Dermal)	Oral NOAEL=5*	Increased skeletal malformations/variations in the rabbit developmental toxicity study. A 21-day dermal toxicity study in rats with a systemic toxicity NOAEL of 500 mg/kg/day and a LOAEL of 3000 mg/kg/day is available. The Committee, however, selected the developmental NOAEL from an oral study because: 1) skeletal malformations were seen following <i>in utero</i> exposure in two species, rats and rabbits; 2) of the concern for the differences in the endpoints seen following oral administration in the developmental toxicity study (skeletal malformations) and dermal administration in the 21-day dermal toxicity study (body weight loss) in the same species (rats); 3) developmental effects were not evaluated in the dermal toxicity study (i.e., the consequence of these effects can not be ascertained for the dermal route of exposure; and 4) the concern for exposure by pregnant occupational workers. The dose and endpoint selected from this study is considered appropriate for short- and intermediate- term dermal exposure risk assessments.
	MOE=100	
Short- and Intermediate-Term (Inhalation)	Oral NOAEL=5*	Increased skeletal malformations/variations in the rabbit developmental toxicity study. A 7 week subchronic inhalation toxicity study in rats with a systemic toxicity LOAEL of 0.01 mg/L (2.62 mg/kg/day) based on histological changes in the kidney (nephropathy and tubular epithelial regeneration) is available in the data base. However, this study is not appropriate for regulatory purposes because the study is classified as supplementary due to technical difficulties. The whole body exposure (as opposed to nose only) and the technical difficulties encountered in the generation of the test material resulted in variable exposure concentrations which in turn may have resulted in the animals not being uniformly exposed to the test material. Therefore, the NOAEL from the developmental toxicity study in rabbits was selected and is considered appropriate for short- and intermediate- term inhalation exposure risk assessments.
	MOE=100	
Long-Term (Dermal & Inhalation)	A dose and endpoint were not identified because of the current use pattern (maximum application rate of 1.5 lb/A per year), handler activities and re-entry worker activities. Since long-term dermal exposure (continuous exposure of greater than 180 days) is not anticipated, this risk assessment is not required.	

* Since an oral NOAEL was selected, a dermal absorption factor of 1% and an inhalation absorption factor of 100% (default value) should be used during route to route extrapolation.

4.0 EXPOSURE ASSESSMENT

4.1 Summary of Registered/Proposed Uses

Triallate [*S*-2,3,3-trichloroallyl diisopropylthiocarbamate] is a preemergent selective herbicide regionally registered for use on barley, lentils, peas (dried and succulent), triticale, and wheat. Triallate is sold in the United States by its basic producer, Monsanto Company, under the trade names Far-Go®, Buckle®, and Avadex®. The 10% granular (G) and 4 lb/gal emulsifiable concentrate (EC) for Far-Go® and Buckle® are the only triallate formulations registered for food/feed uses. Depending on the crop, these formulations may be applied at application rates of 1.0-1.5 lb ai/A as preplant and postplant soil incorporated using ground or aerial equipment. Application is typically made either in the fall or in the spring before targeted weed species germinate. Residue data for sugar beets are discussed in this chapter although sugar beets are not registered for use in the US. A tolerance petition for sugar beets is currently pending. There are no proposed or existing residential uses for these products.

4.2 Dietary Exposure

Regional registration and tolerances (labels restrict the use to the following states: CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY) are currently established under 40 CFR §180.314 (a) for residues of parent triallate in or on the following commodities: barley grain and straw, 0.05 ppm (N); canary grass (annual) seed and straw, 0.05 ppm; lentils and lentil forage and hay, 0.05 ppm (N); peas and pea forage and hay, 0.05 ppm (N); wheat grain and straw, 0.05 ppm (N). No tolerances have been established for processed food/feed or animal commodities. Residue data for sugar beets are discussed in this chapter although sugar beets are not registered for use in the US. A tolerance petition for sugar beets is currently pending. The registrant is not supporting reregistration for canary grass.

4.2.1 Food Exposure

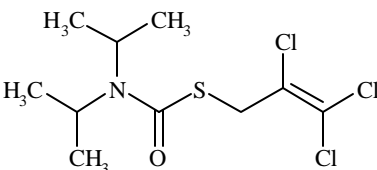
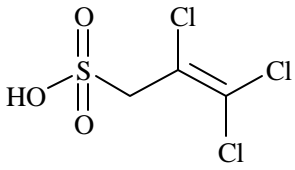
4.2.1.a. Nature of the Residue

Plants: The reregistration requirements for plant metabolism are fulfilled based on acceptable studies conducted on wheat, peas, and sugar beets. In wheat, it was demonstrated that some portion of the radiolabeled triallate is catabolized and subsequently incorporated into natural products. In peas, neither triallate nor any of the trichlorinated 3-carbon metabolites [such as 3-(methylsulfinyl)-1,1,2-trichloro-1-propene; 3-(methylsulfonyl)-1,1,2-trichloro-1-propene; and 2,3,3-trichloro-2-propen-1-ol which were previously reported in rat urine] were identified. The metabolite 2,3,3-trichloroprop-2-enesulfonic acid (TCP SA) was the major residue found in the pea with pod (16% TRR), green vine (40% TRR), and dry hay (21% TRR). Two other minor metabolites, oxalylglucose sulfoxide and sulfone, were also found in dried hay (1% and

13% TRR, respectively); only the sulfoxide was found in green vine (9% TRR). The pea metabolism study demonstrated the incorporation of radioactivity into sugars (mono-, di-, and trisaccharides), amino acids, starch, pectins, lignin and cellulose. Triallate was metabolized in pea via oxidation at the allylic carbon, leading to natural products, or oxidation and hydrolysis at the sulfur atom, leading to metabolites (oxalylglucose sulfoxide and sulfone). The sulfoxide and sulfone metabolites would metabolize to TCPSA. A sugar beet metabolism study submitted and evaluated in conjunction with PP#8F2128 showed that TCPSA was the major residue in sugar beet root (15% TRR) and foliage (55% TRR).

The HED Metabolism Assessment Review Committee (L. Cheng memo of 6/22/98) has determined that only triallate and TCPSA should be regulated and assessed for dietary exposure. The HED Metabolism Committee concluded to regulate on the TCPSA metabolite because it is present at more than 10% of the TRR in the plant metabolism studies, and in the absence of toxicological data for this metabolite, the same toxicity as the parent compound was assumed. The chemical name and structures of triallate residues of concern are depicted in Figure 1.

Figure 1 Chemical Names and Structures of Triallate Residues of Concern in Plant and Animal Commodities.

Common Name Chemical Name	Structure
Triallate <i>S</i> -2,3,3-Trichloroallyl diisopropyl- thiocarbamate	
TCPSA 2,3,3-Trichloroprop-2-enesulfonic acid	

Animals: The reregistration requirements for animal metabolism are fulfilled. Acceptable ruminant and poultry metabolism studies have been submitted and evaluated. In a ruminant metabolism study, a lactating goat was orally administered [¹⁴C]triallate at 14 ppm in the diet for five consecutive days. The total radioactive residues (expressed as triallate equivalents) were 0.177 ppm in milk, 1.08 ppm in liver, 2.46 ppm in kidney, 0.033 ppm in muscle, and 0.017 ppm in omental fat. The parent triallate was identified as a minor component in omental fat (12.4% TRR) and milk (2.3% TRR). The majority of radioactive residues in goat milk and edible tissues were found to be associated with natural constituents.

In a poultry metabolism study, laying hens were orally dosed once daily with [¹⁴C]triallate at approximately 13 ppm in the diet for five consecutive days. The total

radioactive residues (expressed as triallate equivalents) were 0.540 ppm in egg yolk, 0.054 ppm in egg white, 1.29 ppm in liver, 0.042 ppm in breast muscle, 0.049 ppm in thigh muscle, 0.193 ppm in abdominal fat, and 0.100 ppm in skin with fat. The parent triallate was identified in egg yolk (2.8% TRR), abdominal fat (23.7% TRR), and skin with fat (16.5% of TRR). The majority of radioactive residues in poultry eggs and edible tissues were also found to be associated with natural constituents.

Since very little or low levels of triallate were transferred to animal tissues (0.004 ppm in milk and 0.002 ppm in poultry fat), the HED Metabolism Assessment Review Committee (L. Cheng memo of 6/22/98) has concluded that meat, egg and milk tolerances are not required, pending results of the rotational crop studies and reassessment of animal feed tolerances. The Committee's determination was based on the current feed tolerances (expressed in terms of triallate *per se*) and the theoretical maximum dietary burden for livestock animals which is a fraction of the dose administered in the completed goat and chicken metabolism studies.

4.2.1.b. Residue Analytical Methods

Plants: The current PAM Vol. II method is a GC/ECD method (designated as Method A) which is used for analysis of residues of triallate *per se* in/on lentils, peas, and grain and straw of barley and wheat (Pesticide Reg. Sec. 180.314). PAM Vol. II reports the sensitivity of the method (LOQ) as 0.02 ppm.

In conjunction with an ongoing petition (PP#8F2128) for the regional registration of triallate on sugar beets, the registrant has proposed a GC/ECD method (designated as Method RES-099-96, Version No. 2) for tolerance enforcement purposes. The method determines residues of triallate and its TCPSA metabolite. This method has been subjected to a successful independent laboratory validation. The method has also been validated in an Agency study at Beltsville, MD. The laboratory (Analytical Chemistry Branch, BEAD) verified the limits of quantitation (LOQs) to be 0.025 ppm triallate and 0.025 ppm TCPSA in/on sugar beet roots, and 0.05 ppm triallate and 0.20 ppm TCPSA in/on sugar beet foliage. The Beltsville report (7/28/98) also estimated the limits of detection (LODs) to be 0.001 ppm triallate and 0.004 ppm TCPSA in sugar beet root, and 0.005 ppm triallate and 0.04 ppm TCPSA in sugar beet top.

A brief description of the modified method follows. Residues in samples are extracted by homogenization with acetonitrile/water. Solids are removed by filtration and a solution of Na₂SO₄ is added to the extract. The solution is partitioned with isooctane to isolate triallate. The aqueous phase is retained for later isolation of TCPSA. The isooctane phase is concentrated and eluted through a silica gel SPE cleanup column and then analyzed by capillary GC using a ⁶³Ni electron capture detector. The retained aqueous layer is partitioned with methylene chloride, once as a cleanup, and a second time using phase transfer catalyst. The second extract is evaporated, treated with a cation exchange resin, derivatized with triethylorthoformate, eluted through a silica gel SPE cleanup column, and analyzed for ethyl sulfonate by capillary GC using an ⁶³Ni-

ECD. As a confirmatory technique, the conditions for separation on a different GC column (non-polar instead of polar) were provided. Positive residues can be confirmed with this alternate GC column or by GC/MS.

The Agency concludes that Monsanto's GC/ECD method (designated as Method RES-099-96, Version No. 2) is adequate for data gathering and enforcement purposes. Radiovalidation of the proposed method using weathered samples from plant metabolism studies are not required because the Agency has determined that the initial extraction procedures of residues in representative samples collected from plant metabolism studies are similar to those of the proposed enforcement method. This method have recently been submitted and forwarded to FDA for evaluation and inclusion in PAM Volume II.

Animals: An enforcement method for determination of residues of triallate and its TCPSA metabolite is not required because tolerances for eggs, milk, and animal tissues have not been established and are not required for reregistration purposes. Samples of eggs, milk, and tissues collected from animal feeding studies were analyzed for residues of triallate and its TCPSA metabolite using an adequate GC/ECD method with a detection limit of 0.01 ppm.

4.2.1.c. Multi-Residue Method

The 2/97 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that residues of triallate are completely recovered (>80%) using Multiresidue Method Sections 302 (Luke Method; Protocol D), 303 (Mills, Onley, Gaither Method; Protocol E, non-fatty foods), and Section 304 (Mills Method; Protocol E, fatty foods).

Multiresidue methods test data for determination of TCPSA in/on plant commodities have recently been submitted and forwarded to FDA for evaluation and inclusion in PAM Volume I, Appendix I.

4.2.1.d. Storage Stability

Plants: Adequate data concerning the storage stability of triallate and its TCPSA metabolite in/on plant commodities have been submitted and evaluated. Residues of triallate have been demonstrated to be stable under frozen storage condition in/on the following representative RACs: wheat forage (for up to 1,732 days), wheat straw (for up to 645 days), barley straw (for up to 689 days), dry bean hay (for up to 731 days), dry bean vines (for up to 653 days), and succulent bean hay (for up to 752 days). Residues of TCPSA metabolite have been demonstrated to be stable under frozen storage condition in/on the following representative RACs: wheat forage (for up to 1736 days), wheat straw (for up to 659 days), wheat grain (for up to 719 days), barley

straw (for up to 702 days), dry bean hay (for up to 741 days), dry bean vines (for up to 682 days), succulent bean seeds/pods (for up to 964 days), and succulent bean hay (for up to 759 days). Residues of triallate and TCPSA are stable for up to 314 days in sugar beet tops and for up to 376 days in sugar beet root. The storage intervals and conditions of RAC samples collected from the respective field trials are validated by acceptable storage stability data.

Adequate storage stability data are available for wheat processed fractions. Residues of triallate and its TCPSA metabolite are stable under frozen storage conditions in wheat bran, shorts, and flour for at least 5 months. Although storage stability data for middlings were not submitted, the Agency believes that triallate residues of concerns would also be stable in this processed fraction.

Animals: Adequate data concerning the storage stability of triallate and its TCPSA metabolite in animal commodities have been submitted and evaluated. Residues of triallate and its TCPSA metabolite have been demonstrated to be stable under frozen storage condition in/on the following animal matrices: chicken muscle (for up to 611 days), eggs (for up to 615 days), milk (for up to 611 days), beef muscle (for up to 651 days), beef fat (for up to 658 days), beef liver (for up to 647 days), beef kidney (for up to 647 days), and pork kidney (for up to 616 days). The storage intervals and conditions of animal tissue samples collected from the respective animal feeding studies trials are validated by acceptable storage stability data.

4.2.1.e. Crop Field Trials

Current labels restrict use of triallate to the following states: CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY. As part of tolerance reassessment, tolerances with regional registration will be recommended for these states. The registrant has indicated that use of triallate on canary grass will not be supported for reregistration, and has deleted this use site from all triallate end-use product labels. Overall, the available data indicate that residues of the metabolite TCPSA were generally higher than the parent. There appears to be no significant differences in the results of field trials using the G and EC formulations. A discussion of the adequacy of the available field trial data for each crop follows. Triallate is not currently registered for use on sugar beets in the US, but a petition for tolerances is pending.

Barley: The reregistration requirements for magnitude of the residue in/on barley *grain* and *straw* are fulfilled pending tolerance adjustments. Barley *hay* has now been included in Table 1 (OPPTS GLN 860.1000) as a significant livestock feed item. The requested wheat hay data may be translated to barley hay since the registered uses of triallate on barley and wheat are identical. In field trials conducted in MT and WA, representative G and EC formulations were applied according to label directions at 1.5,

2.0, 2.5, and 3.0 lb ai/A (1x, 1.3x, 1.7x, and 2x the maximum registered rate, respectively). Barley grain and straw were harvested at 110 to 113 days posttreatment, and forage was harvested 54 to 59 days posttreatment. The harvested samples were analyzed for residues of triallate and its TCPSA metabolite using an adequate GC/ECD method with a detection limit of 0.01 ppm. The results of the barley field trials, reflecting treatment at 1x, are presented in Table 4. Refer to "Tolerance Reassessment Summary" section for recommendations regarding appropriate tolerance levels for barley grain and straw.

Table 4. Residues of triallate and its TCPSA metabolite in/on barley commodities following application of representative G and EC formulations at 1.5 lb ai/A (1x) (MRID 40117702).

Barley Matrix ¹	Residue Levels (ppm)		
	Triallate	TCPSA	Maximum Combined Residues
Grain	<0.01	<0.01	<0.02
Straw	0.01-0.03	0.05-0.23	0.26
Forage	0.04-0.06	0.10-0.23	0.29

¹ According to Table 1 (OPPTS 860.1000), the RACs of barley are grain, hay, and straw. Barley forage has been deleted from Table 1 (OPPTS GLN 860.1000) .

Lentils: According to 40 CFR §180.1(h), the available dried pea field trial data may be translated to lentils since the registered use patterns of peas and lentils are identical.

Peas (succulent/dried): The reregistration requirements for magnitude of the residue in/on *peas (succulent and dried)*, *pea vines*, and *pea hay* are fulfilled pending tolerance adjustments. Field trials were conducted on succulent peas (ND and WA, 2 field trials) and on dry peas (MN and WI, 3 field trials). Representative G and EC formulations were applied according to label directions at 1.25 and 2.5 lb ai/A (- 1x and 2x the maximum registered rate). Treated samples were harvested at the following posttreatment intervals: 62-76 days for succulent pea seed/pods and straw; 48-50 days for succulent pea vines; 79-110 days for dry pea seed and straw; and 51-53 days for dry pea vines. The harvested samples were analyzed for residues of triallate and its TCPSA metabolite using an adequate GC/ECD method with a detection limit of 0.01 ppm. The results of the pea field trials, reflecting treatment at - 1x, are presented in Table 5. Refer to "Tolerance Reassessment Summary" section for recommendations regarding appropriate tolerance levels for peas (succulent and dried), pea vines, and pea hay.

Table 5. Residues of triallate and its TCPSA metabolite in/on pea commodities following application of representative G and EC formulations at 1.25 lb ai/A (- 1x) (MRID 40117704).

Pea Matrix	Residue Levels (ppm)		
	Triallate	TCPSA	Maximum Combined Residues
Succulent (green) Peas			
Seed and pods	<0.01	0.06, 0.06, 0.10, 0.11	<0.12
Vines	<0.01-0.02	0.19-0.37	<0.39
Straw	<0.01	0.35-0.66	<0.67
Dry Peas			
Seed	<0.01	<0.01	<0.02
Vines	<0.01	0.04-0.26	<0.27
Straw	<0.01	0.05-0.35	<0.36

Wheat: The reregistration requirements for magnitude of the residue in/on wheat *grain*, *forage*, and *straw* are fulfilled pending tolerance adjustments. Wheat *hay* and *aspirated grain fractions* have now been included in Table 1 (OPPTS GLN 860.1000) as significant livestock feed items. Therefore, data depicting the magnitude of the residues of triallate and its TCPSA metabolite in/on wheat hay are required; details of data requirements for wheat hay are specified in Table B. Data on wheat aspirated grain fractions are not required because the registered use of triallate on wheat involves preemergence application (before the reproductive stage of the crop begins), and triallate residues of concern in wheat grain were mostly below the LOD of the analytical method.

Eleven field trials were conducted on spring wheat (ND, MT, CA and KS) and on winter wheat (CA, KS, MT, OK, WA and NY). Representative G and EC formulations were applied according to label directions at 1.5, 2.0, 2.5, and 3.0 lb ai/A (1x, 1.3x, 1.7x, and 2x the maximum registered rate, respectively). Harvest time varied considerably (36-312 days posttreatment) depending on planting time and wheat matrix. Wheat RACs were analyzed for residues of triallate and its TCPSA metabolite using an adequate GC/ECD method with a detection limit (LOD) of 0.01 ppm. The results of the wheat field trials, reflecting treatment at 1.0x, are presented in Table 6. Refer to "Tolerance Reassessment Summary" section for recommendations regarding appropriate tolerance levels for wheat grain, forage, and straw.

Table 6. Residues of triallate and its TCPSA metabolite in/on wheat commodities following application of representative G and EC formulations at 1.5 lb ai/A (1x) (MRID 40117701).

Wheat Matrix ¹	Residue Levels (ppm)		
	Triallate	TCPSA	Maximum Combined Residues
Grain	<0.01-0.01	<0.01-0.03	0.04
Straw	0.01-0.03	0.02-0.91	0.94
Forage	<0.01-0.12	0.01-0.30	<0.31

¹ According to Table 1 (OPPTS 860.1000), the RACs of wheat are grain, forage, hay, straw, and aspirated grain fractions.

According to 40 CFR §180.1(h), the available wheat field trial data may be translated to triticale since the registered use patterns of wheat and triticale are identical.

Sugar Beets: Ten field trials were conducted in ID, MN, ND, CA, NE, WY. Representative G and EC formulations were applied according to proposed label directions from 1 to 10 lbs ai/A (0.5 x to 5x; 2 lbs ai/A = 1x rate), 0 to 11 days prior to planting using ground application techniques. Roots and foliage samples were collected at harvest. The harvested samples were analyzed for residues of triallate and its TCPSA metabolite using an adequate GC/ECD method with a detection limit (LOD) of 0.01 ppm. The results of the sugar beet trials reflecting application at the proposed 1x rate are shown in Table 7. Refer to "Tolerance Reassessment Summary" section for recommendations regarding appropriate tolerance levels for sugar beets.

Table 7. Residues of Triallate and its TCPSA metabolite in/on sugar beet commodities following application of representative G and EC formulations at 2.0 lbs ai/A (1x) (MRID 406922-01 and 406922-06).

Formulation	Residue Levels (ppm)		
	Triallate	TCPSA	Maximum Combined Residues
Sugar Beet Root			
10G	<0.01, 0.01, 0.03	<0.01	<0.04
2 EC	<0.01, 0.01	<0.01	<0.02
Sugar Beet Top			
10G	<0.01, 0.01	0.02, 0.03, 0.04, 0.05, 0.07, 0.10, 0.13, 0.24, 0.24, 0.30	<0.31
2 EC	<0.01	<0.01, 0.02, 0.02, 0.08, 0.08, 0.09, 0.12, 0.13, 0.16, 0.16	<0.17

4.2.1.f. Processed Food/Feed

An acceptable wheat processing study has been submitted and evaluated. In this study, wheat was treated at 2.5 lb ai/A (1.7x the maximum registered rate), and samples of treated whole grain were processed into flour, bran, and shorts. Residues were determined using an acceptable GC/ECD method with a detection limit of 0.01 ppm. The results of the wheat processing study are presented in Table 8.

Table 8. Results of a wheat processing study (MRID 40473801).

Commodity	Residues (ppm)			Concentration Factor		
	Triallate	TCPSA	Combined	Triallate	TCPSA	Combined
Whole grain	<0.01	0.03	<0.04	--	--	--
Flour	<0.01	0.01	<0.02	1.0	0.3	0.5
Wheat Mill by-products	<0.01	0.07	<0.08	1.0	2.3	2.0
Bran	<0.01	0.09	<0.10	1.0	3.0	2.5
Shorts	<0.01	0.07	<0.08	1.0	2.3	2.0

The Agency has previously determined that although the potential for concentration of residues in middlings was not investigated, no additional data on this processed fraction will be required since middlings are not a major end product, but an intermediate in producing bran and shorts. Refer to "Tolerance Reassessment Summary" section for a discussion regarding the need for tolerances on bran and shorts based on the observed concentration factors.

A barley processing study is required for reregistration. [According to Triallate Phase 4, the registrant indicated in the Phase 2 Response that a barley processing study is available, but no summary was provided. A search of PDMS showed no barley processing study. The processed fractions listed in Table 1 (OPPTS GLN.860.1000) for barley and wheat are different.]

Two sugar beet processing studies were submitted to the Agency. Sugar beet root were treated at 10 lb ai/A (5x) and were processed in a pilot facility under conditions similar to commercial processing. Samples of whole roots, dried pulp, white (refined) sugar and molasses were analyzed for residues of triallate and TCPSA. Results from the processing studies are shown in Table 9.

Table 9. Residues of Triallate and its TCPSA metabolite in/on sugar beet and processed commodities following application of triallate at 10 lbs ai/A (5x) (MRID 412799-01).

Sugar Beet Matrix	Residue Levels (ppm)		
	Triallate	TCPSA	Maximum Combined Residues
Baker, MN			
Roots	0.12, 0.05	0.02, 0.03	0.14, 0.08
Dried Pulp	0.27	0.03	0.30
Sugar	<0.01	<0.01	<0.02
Molasses	<0.01	0.01	<0.02
Colfax, ND			

Sugar Beet Matrix	Residue Levels (ppm)		
	Triallate	TCPSA	Maximum Combined Residues
Roots	0.05, 0.01	0.01, 0.02	0.06, 0.03
Dried Pulp	0.07	0.01	0.08
Sugar	<0.01	<0.01	<0.02
Molasses	<0.01	0.02	<0.03

As can be seen from Table 9, residues from the processing study conducted in ND detected very low amounts of triallate and its metabolite in the sugar beet root. Therefore, for purposes of risk assessment HED will only consider the study conducted in MN for anticipated residue calculation. The processing factors are shown in Table 10.

Table 10. Processing factors of Triallate and its TCPSA metabolite in/on sugar beet processed commodities.

Sugar Beet Matrix	Total Triallate + TCPSA Residues (ppm)	Processing Factor
Roots	0.11	--
Dried Pulp	0.30	2.7x
Sugar	<0.02	<0.18x
Molasses	<0.02	<0.18x

Sugar beet tops, molasses, and dried sugar beet pulp may be fed to livestock. However, since triallate will be regionally registered, exposure of triallate residues to livestock is minimal when compared to the already registered uses (wheat, barley, peas).

4.2.1.g. Meat, Milk, Poultry, Eggs

Acceptable ruminant and poultry feeding studies have been submitted and evaluated in conjunction with previous triallate petitions (PP#8F2128, PP#1F2460, and PP#6F3346; CB Nos. 840-845; 8/18/86, M. Firestone). The salient features of these feeding studies are presented below. A discussion regarding the need for animal commodity tolerances follows.

Milk, fat, meat, and meat byproducts of ruminants: Triallate, a preemergence selective herbicide, is not registered for direct animal treatments on cattle, goats, hogs, horses, or sheep. However, triallate residues of concern may occur indirectly in milk and edible tissues of livestock as a result of ingestion of feed items such as: barley grain

and straw; pea vines and hay; and wheat grain and straw. Using the reassessed tolerances for these livestock feed items, the maximum theoretical dietary burdens of triallate to beef and dairy cattle are tentatively calculated to be 0.354 and 0.625 ppm, respectively (see table below). The dietary burden calculations are tentative because field trial data remain outstanding for a few potential feed items (i.e., barley hay and wheat hay); in addition, the data requirements for limited/extensive field rotational crops studies remain outstanding.

Table 11. Calculation of maximum ruminant dietary burden for triallate.

Feed Commodity	Reassessed Tolerance (ppm)	% Dry Matter	Beef Cattle		Dairy Cattle	
			% of Diet	Burden (ppm)	% of Diet	Burden (ppm)
Pea, hay	1.0	88	25	0.284	50	0.568
Barley, grain	0.05	88	50	0.028	40	0.023
Barley, straw	0.3	89	10	0.034	10	0.034
Wheat, grain	0.05	89	15	0.008	--	--
TOTAL			100	0.354	100	0.625

In a dairy cow feeding study, cows were fed capsules containing a mixture of triallate:TCPSA (1:1) at dose levels of 1, 3, and 10 ppm (16x for dairy cattle and 28x for beef cattle) each component (i.e., total dose of 2, 6, and 20 ppm, respectively). Sixteen cows were divided into three treatment groups plus a control group. After 28 days of dosing, three of the four cows from each group were sacrificed, and tissue samples were collected; the remaining animals were sacrificed after administration of the final dose. Milk and tissue samples were analyzed for residues of triallate and its TCPSA metabolite using an adequate GC/ECD method with a detection limit of 0.01 ppm. Only when residue levels were above the analytical method's LOD were samples from the next highest dose analyzed. The results of the dairy cow feeding study are presented in Table 12.

Table 12. Residues of triallate and its TCPSA metabolite in milk and tissues of dairy cows fed capsules containing a mixture of triallate:TCPSA (1:1) at dose levels of 3 and 10 ppm each component (MRID 00152876).

Sample	Dose Level (ppm)	Maximum Residue Level (ppm)		
		Triallate	TCPSA	Combined
Milk (Day 1 - 28)	10	<0.01	<0.01	<0.02
Muscle	10	<0.01	<0.01	<0.02
Liver	10	<0.01	<0.01	<0.02
Kidney	3	<0.01	0.10	<0.11
Kidney	10	<0.01	0.05	<0.06
Fat	3	0.01	0.05	0.06
Fat	10	0.03	0.15	0.18

The dairy cow feeding study shows that it is not possible to establish with certainty whether finite residues of triallate will be incurred in milk, muscle, and liver, but there is no reasonable expectation of finite residues (category 3 of 40 CFR §180.6(a)) in these three matrices. Therefore, tolerances are not required for milk, muscle, and liver.

Eggs, fat, meat, and meat byproducts of poultry. There are no registered direct animal treatments for triallate on poultry. The only poultry feed items with triallate uses include barley grain and wheat grain. The maximum theoretical dietary burden of triallate to poultry is tentatively calculated to be 0.05 ppm (see Table 13).

Table 13. Calculation of maximum theoretical dietary burden of triallate to poultry.

Feed item	Reassessed Tolerance, ppm	% in Diet	Dietary burden, ppm
Barley, grain	0.05	75	0.0375
Wheat, grain	0.05	25	0.0125
Total		100	0.050

In a poultry feeding study, eighty laying hens were divided into three treatment groups plus a control group. The treated hens were dosed with gelatin capsules at levels corresponding to a diet containing a 1:1 mixture of triallate:TCPSA at 1, 3, and 10 ppm (200x dietary burden) each component (i.e., total dose of 2, 6, and 20 ppm, respectively). After 28 days of dosing, 10 hens from each group were sacrificed, and tissue samples were collected; the remaining hens were sacrificed after a 28-day withdrawal period. Eggs were collected throughout the study administration of the final dose. Eggs and poultry tissue samples were analyzed for residues of triallate and its TCPSA metabolite using an adequate GC/ECD method with a detection limit of 0.01 ppm. Only when residue levels were above the analytical method's LOD were samples from the next highest dose analyzed. The results of the poultry feeding study are presented in Table 14.

Table 14. Residues of triallate and its TCPSA metabolite in eggs and tissues of poultry fed capsules containing a mixture of triallate:TCPSA (1:1) at dose levels of 1, 3, and 10 ppm each component (MRID 00150272)

Sample	Dose Level (ppm)	Maximum Residue Level (ppm)		
		Triallate	TCPSA	Combined
Eggs	10	0.01	0.03	0.04
Eggs	3	<0.01	<0.01	<0.02
Muscle	10	<0.01	<0.01	<0.02
Liver	10	<0.01	<0.01	<0.02
Kidney	10	<0.01	<0.01	<0.02
Fat	10	0.04	<0.01	<0.05
Fat	3	0.01	<0.01	<0.02
Fat	1	<0.01	<0.01	<0.02

The poultry feeding data show that it is not possible to establish with certainty whether finite residues of triallate will be incurred, but there is no reasonable expectation of finite residues (category 3 of 40 CFR §180.6(a)). Therefore, tolerances are not required for eggs and poultry tissues.

4.2.1.h. Water, Fish, and Irrigated Crops

Triallate is presently not registered for direct use on water and aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics. EFED will provide levels for residues of triallate and TCPSA in drinking water.

4.2.1.i. Food Handling

Triallate is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

4.2.1.j. Confined/Field Accumulation in Rotational Crops

An acceptable confined rotational crop study has been submitted to satisfy reregistration requirements under OPPTS GLN 860.1850. The confined rotational crop study indicates that the metabolism of triallate in rotational crops is similar to that in primary crops (pea and wheat). Radioactive residues (expressed in terms of [¹⁴C]triallate equivalents) accumulated at levels above 0.01 ppm in/on all commodities of lettuce, radish, and wheat that were planted in sandy loam soil 30/76, 120, and 365 days after treatment (DAT) of the soil with [¹⁴C]triallate at 1.95 lb ai/A (1.3x the maximum seasonal rate registered for annual crops). In general, residue accumulation

declined from shorter to longer rotation intervals. Radioactive residues remained detectable in all rotated plant matrices at the 365-DAT rotation interval.

The study adequately characterized/identified the majority of radioactive residues. Triallate and its TCPSA metabolite were the only identified residues in any of the crop matrices. A major amount of radioactivity (5-25% TRR) was also characterized as a polar unknown. Several approaches (such as acetylation, derivatization, acid/base hydrolysis, and molecular weight size exclusion) were used in the attempt to further identify the polar unknown residues. Based on these results, the registrant concluded that the polar unknown is polysaccharide in character.

Because triallate residues of concern (triallate and its TCPSA metabolite) were detected in rotational crop commodities, limited field rotational crop studies must be conducted. The limited field trials should be conducted on representative crops of the root and tuber vegetables, leafy vegetables, and small grains at two sites per crop for a total of six trials. The six trials should be conducted on crops which the registrant intends to have as rotational crops on the product labels. Samples should be analyzed for residues of triallate and its TCPSA metabolite. If these limited field trials indicate that quantifiable triallate residues of concern will occur, then extensive field rotational crop trials and rotational crop tolerances will be required. The registrant should consult OPPTS GLN 860.1900 (Field Accumulation in Rotational Crops) for additional guidance concerning this requirement.

The need for rotational crop tolerances and restrictions will be determined following submission of the required field rotational crop studies.

4.2.1.k. Tolerance Reassessment Summary

The established tolerances [40 CFR §180.314, (a)] for residues of triallate in/on plant commodities are currently expressed in terms of triallate *per se*. No tolerances have been established for animal or processed food/feed commodities. The triallate tolerance expression needs to be revised in order to reflect the HED's Metabolism Assessment Review Committee determination that triallate and its TCPSA metabolite should be regulated and assessed for dietary exposure.

The Agency has updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). As a result of changes to Table 1, triallate tolerances for certain commodities which have been removed from Table 1 need to be revoked, and some commodity definitions must be corrected. In addition, tolerances for commodities which will not be supported for

reregistration need to be revoked. A summary of triallate tolerance reassessments is presented in Table 15.

Tolerances Listed Under 40 CFR §180.314 (a): The tolerances listed under 40 CFR §180.314 (a) should be moved to §180.314 (c) to specify regional registration of triallate. Uses of the registered G and EC formulations of triallate, when applied according to label directions, are permitted only in the states of CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY.

Sufficient data have been submitted to reassess the established tolerances for the following plant commodities, **as defined:** barley, grain; barley, straw; peas; peas, forage; peas, hay; wheat, grain; and wheat, straw. The available data from field trials reflecting the maximum registered use patterns suggest that the combined residues of triallate and its TCPSA metabolite will exceed the currently established tolerance level of 0.05 ppm for most of the above commodities.

The established tolerances for the following commodities, **as defined**, should be revoked: grass, canary, annual, seed; grass, canary, annual, straw; lentils; and lentils, hay. The use of triallate on canary grass is not being supported for reregistration, and this site has been removed from all of Monsanto's end-use products containing triallate as the active ingredient. Lentils may be classified as peas in accordance with 40 CFR §180.1(h), and adequate data are available for peas. Lentil forage and hay are no longer considered significant livestock feed items and have been deleted from Table 1 (OPPTS GLN 860.1000).

New Tolerances Needed Under 40 CFR §180.314 (c): As a result of changes in Table 1 (OPPTS GLN 860.1000), field residue data and tolerances are required for barley hay, wheat forage, and wheat hay. The requested data for wheat hay may be translated to barley hay since the registered uses of triallate on barley and wheat are identical. Adequate data are available for wheat forage and these data may be the basis for tolerance establishment.

The available wheat processing data indicate that the combined residues of triallate and TCPSA did not concentrate in flour but concentrated in bran (2.5x) and shorts (2.0x). These fractions were processed from whole wheat grain bearing nondetectable residues of triallate (<0.01 ppm) and detectable residues of TCPSA (0.03 ppm) following treatment at 1.7x the maximum registered rate. The HAFT (combined residues) of wheat grain from trials reflecting 1x treatment is <0.02 ppm. Based on this HAFT and the observed concentration factors, the maximum expected combined residues are <0.05 ppm for bran (2.5 x <0.02) and <0.04 ppm for shorts (2.0 x <0.02 ppm). These maximum expected residues are equal or less than the reassessed

tolerance of 0.05 ppm for wheat grain. Therefore, tolerances for the combined residues of triallate and TCPSA in wheat bran and shorts need not be proposed.

The reregistration requirements for limited/extensive field rotational crop studies have not been fulfilled. Depending on the outcome of these required studies, rotational crop tolerances may be required.

The expected dietary burdens of triallate to beef/dairy cattle and poultry animals were recalculated following tolerance reassessment of livestock feed items. The available animal feeding studies suggest that it is not possible to establish with certainty whether finite residues of triallate will be incurred, but there is no reasonable expectation of finite residues (Category 3 of 40 CFR §180.6). Therefore, tolerances are not required for milk, eggs, and animal tissues.

Pending Active Tolerance Petition: FAP#8F2128: Monsanto has proposed the establishment of regional tolerances for the combined residues of triallate and its TCPSA metabolite in/on sugar beet roots at 0.1 ppm, sugar beet foliage at 0.5 ppm, and dried sugar beet pulp at 0.2 ppm. Pending adequate resolution of issues relating to drinking water levels of comparison (DWLOCs), HED could recommend for the establishment of the proposed tolerances (DP Barcode D237774, S. Chun, 1/12/98).

Table 15 Tolerance Reassessment Summary for Triallate. All Tolerances should be established under 40 CFR §180.314 (c)

Commodity	Established Tolerance ¹ (ppm)	Reassessed Tolerance ² (ppm)	Comments [<i>Correct Commodity Definition</i>]
Tolerance Listed Under 40 CFR §180.314 (c)			
Barley, grain	0.05 (N)	0.05	The available data, reflecting the maximum registered use pattern, indicate that residues of triallate and its TCPSA metabolite were <0.01 ppm each in/on barley grain.
Barley, straw	0.05 (N)	0.3	The available data, reflecting the maximum registered use patterns, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.26 ppm in/on barley straw.
Grass, canary, annual, seed	0.05	Revoke	Monsanto has indicated that it will not support the use of triallate on canary grass, and this site has been removed from all of Monsanto's end-use products containing triallate as the active ingredient.
Grass, canary, annual, straw	0.05		
Lentils	0.05 (N)	Revoke	Since a tolerance for peas is established, the tolerance for lentils should be revoked. According to 40 CFR §180.1(h), the established tolerance for peas will apply to lentils.
Lentils, forage	0.05 (N)	Revoke	

Lentil forage and hay are no longer considered significant livestock feed items and have been removed from Table 1 (OPPTS GLN 860.1000).

Commodity	Established Tolerance ¹ (ppm)	Reassessed Tolerance ² (ppm)	Comments [<i>Correct Commodity Definition</i>]
Lentils, hay	0.05 (N)	Revoke	
Peas [<i>Pea, succulent</i>]	0.05 (N)	0.2	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.12 ppm in/on the seed and pods of succulent peas and <0.02 ppm in/on the seed and pods of dried peas.
Peas [<i>Pea, dry</i>]	0.05 (N)	0.2	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.12 ppm in/on the seed and pods of succulent peas and <0.02 ppm in/on the seed and pods of dried peas.
Peas, forage [<i>Pea, field, vines</i>]	0.05 (N)	0.5	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.39 ppm in/on the vines of succulent peas and 0.27 ppm in/on the vines of dried peas.
Peas, hay [<i>Pea, field, hay</i>]	0.05 (N)	1.0	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.73 ppm in/on the straw of succulent peas and 0.36 ppm in/on the straw of dried peas.
Wheat, grain	0.05 (N)	0.05	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.04 ppm in/on wheat grain.
Wheat, straw	0.05 (N)	1.0	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.94 ppm in/on wheat straw.
New Tolerances Needed Under 40 CFR §180.314 (c)			
Barley, hay	--	TBD ³	The requested data for wheat hay will be translated to barley hay.
Wheat, forage	--	0.5	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of triallate and its TCPSA metabolite were 0.42 ppm in/on wheat forage.
Wheat, hay	--	TBD	Additional data are needed.
Proposed Tolerances Under 40 CFR §180.314 (c)			
Sugar Beet, root	--	0.1	No additional data are needed.
Sugar Beet, top	--	0.5	No additional data are needed.
Sugar Beet, pulp	--	0.2	No additional data are needed.

- ¹ The established tolerance is expressed in terms of triallate *per se*.
² The reassessed tolerance is expressed in terms of the combined residues of triallate and its TCPSA metabolite.
³ TBD = To be determined. Reassessment of tolerance(s) cannot be made at this time because additional data are required.

4.2.1.l. CODEX Harmonization

There are no Codex MRLs for triallate; therefore, no questions of compatibility with U.S. tolerances exists.

4.2.1.m. Anticipated Residues

Table 16 contains the anticipated residues (ARs) which should be used for acute and chronic dietary risk assessment for triallate for wheat, barley, dry pea, and sugar beets. Since wheat, barley, dry peas, and sugar beets are considered blended commodities, the ARs for chronic and acute analyses will be the same. For the purposes of this assessment, residue field trial data were used for the chronic and acute AR calculations.

Wheat PDP monitoring data were available for wheat. These data were not used for the AR calculation for wheat because PDP does not analyze for the TCPSA metabolite. All of the samples analyzed by PDP reported non-detectable residues of parent triallate. Field trial samples were analyzed for both triallate and the TCPSA metabolite and there were measurable residues in these.

FDA monitoring data for peas are also available. However, these data were not used in the AR calculation for peas because very few samples were analyzed, and analyses determined the parent compound only. All of the samples were non-detectable. Available field trial data for peas also analyzed the TCPSA metabolite with measurable residues.

For sugar beets, available field trial data analyzed parent triallate and TCPSA residues, and it was used for chronic and acute anticipated residues calculation.

For all the samples that were non-detectable, 1/2 LOD (0.005 ppm) was used as the residue value.

Table 16. Anticipated Residues for Triallate Acute and Chronic Dietary Risk Assessment

Commodity	Anticipated Residue (ppm)	% Crop Treated		Concentration Factor
		Estimated Maximum ¹	Weighted Average ^{2,3}	
wheat grain	0.01	8	6	--
wheat flour	--	8	6	0.5x
wheat bran	--	8	6	2.5x
wheat shorts	--	8	6	2.0x
wheat mill byps	--	8	6	2.0x
barley	0.01	13	9	--
barley flour	--	13	9	0.5x
barley bran	--	13	9	2.5x
dry pea	0.01	30	13	--
sugar beet tops	0.11	21	21	
sugar beet root	0.008	21	21	
sugar beet molasses	--	21	21	0.18x
sugar beet sugar	--	21	21	0.18x
sugar beet dried pulp	--	21	21	2.7x

¹ Estimated maximum percent crop treated will be used for acute DEEM runs.

² Weighted average percent crop treated will be used for chronic DEEM runs.

³ This percent of crop treated will also be used for the cancer dietary risk assessment.

Succulent (green) peas are not considered a blended commodity. Therefore, acute and chronic ARs will be different. For **succulent (green) peas** an AR value of 0.09 ppm (average from field trials) should be used for **chronic** dietary risk assessment with a percent of crop treated of 4%. For the **acute** dietary risk assessment, the residue data file should be constructed using the following values for non-zeros: 0.11 ppm, 0.12 ppm, 0.07 ppm, 0.07 ppm. Note that the percent of crop treated for acute dietary risk is 12%.

4.2.1.n. Dietary Exposure and Risk Analysis

A dietary exposure analysis using the Dietary Exposure Evaluation Model (DEEM™) was completed (Memo, J. Morales, 10/12/99) for a refined Tier 3 approach for acute, chronic (non-cancer), and cancer dietary exposure. The DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-91 Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. For all dietary analyses, anticipated residues and percent of crop treated data were used, as previously

stated. HED's level of concern for acute and chronic dietary risk is >100% of the aPAD and cPAD.

Acute Dietary Exposure and Risk

Two acute probabilistic/Monte Carlo dietary exposure analyses were performed as recommended by the HIARC. Table 17 and 18 summarized the results for the General population and for females 13-50 years, respectively. It should be noted in Table 17 that the risk for all ethnic populations is not higher than that for the general population.

Table 17. Acute Probabilistic/Monte Carlo Dietary Exposure Results for Triallate for the General Population.

Subgroups	95th Percentile Exposure (% aPAD)	99th Percentile Exposure (% aPAD)	99.9th Percentile Exposure (% aPAD)
U.S. Population	0.000003 (<1)	0.000029 (<1)	0.000268 (<1)
All infants (<1 year)	0.000005 (<1)	0.000021 (<1)	0.000736 (<1)
Nursing infants (<1 year)	0.000002 (<1)	0.000003 (<1)	0.000048 (<1)
Non-nursing infants (<1 year)	0.000005 (<1)	0.000028 (<1)	0.000751 (<1)
Children (1-6 years)	0.000005 (<1)	0.000076 (<1)	0.000650 (<1)
Children (7-12 years)	0.000004 (<1)	0.000051 (<1)	0.000349 (<1)

Table 18. Acute Probabilistic/Monte Carlo Dietary Exposure Results for Triallate for Females.

Subgroups	95th Percentile Exposure (% aPAD)	99th Percentile Exposure (% aPAD)	99.9th Percentile Exposure (% aPAD)
Females (13+ /pregnant/not nursing)	0.000002 (<1)	0.000027 (<1)	0.000204 (1.2)
Females (13+/nursing)	0.000003 (<1)	0.000106 (<1)	0.000305 (1.8)
Females (13-19 years/not pregnant/not nursing)	0.000002 (<1)	0.000005 (<1)	0.000221 (1.3)
Females (20+ years/not pregnant/not nursing)	0.000002 (<1)	0.000026 (<1)	0.000204 (1.2)

Subgroups	95 th Percentile Exposure (% aPAD)	99 th Percentile Exposure (% aPAD)	99.9 th Percentile Exposure (% aPAD)
Females (13-50 years)	0.000002 (<1)	0.000013 (<1)	0.000196 (1.2)

The percent acute population adjusted doses (PADs) were below HED's level of concern (2% of aPAD) at the 99.9th percentile of exposure for the females 13+ subgroup and <1% aPAD for the general population. Therefore, the acute dietary risk associated with the uses supported through reregistration and the proposed use on sugar beets of triallate is below the Agency's level of concern.

Chronic and Cancer Dietary Exposure and Risk

The chronic (non-cancer) and cancer DEEM[™] analyses used mean consumption (3 day average). Anticipated residues and percent crop treated information were used. Table 19 summarizes the chronic dietary exposure and includes the U.S. general population and other subgroups. The other subgroups included are all infant and children subgroups and the highest dietary exposures for the respective adult population subgroups (i.e., females and the other general population subgroup higher than U.S. population).

Table 19. Chronic Dietary Exposure Results for Triallate.

Subgroups	Chronic Total Exposure (mg/kg/day)	Chronic Risk (% cPAD)
U.S. Population	0.000001	<1 %
Non-nursing infants (< 1 year old)	0.000003	<1 %
Children (1-6 years old)	0.000003	<1 %
Females (13-19 years old/not pregnant/not nursing)	0.000001	<1 %
Males (13-19 years old)	0.000001	<1 %

The FQPA Safety Factor was removed (equivalent to a factor of 1x) for chronic exposures. Therefore the chronic PAD and the chronic RfD are identical. All chronic (non -cancer) %PADs for all subgroups were < 1%. The results of the chronic dietary analysis indicate that the chronic dietary risk associated with the uses supported through reregistration and the proposed use on sugar beets of triallate is below the Agency's level of concern.

Cancer Dietary Risk:

The Agency generally considers 1×10^{-6} as negligible risk (i.e., less than 1 in 1 million) for cancer. The results of this analysis indicate that the cancer dietary risk of 7.1×10^{-8} associated with the uses supported through reregistration and the proposed use on sugar beets of triallate is below the Agency's level of concern.

Subgroup	Exposure (mg/kg/day)	Lifetime Risk Estimate ¹
U.S. Population (48 states)	0.000001	7.1×10^{-8}

$$LifetimeRiskEstimate = 70 \text{ year Lifetime Exposure (mg/kg/day)} \times Q_1^C$$

$$= (0.000001 \text{ mg/kg/day}) \times (7.17 \times 10^{82} \text{ (mg/kg/day)}^{81})$$

4.2.2 Water

All information for surface and ground water were provided by EFED (Memo, J. Hetrick et. al., 2/25/99; amended 3/17/99, 12/22/99 and 3/28/2000).

Tier I EECs for triallate residues (triallate+TCPSA) were calculated for surface water and ground water. Based on EFED's assessment, Tier 1 model estimated acute and non-cancer triallate residue concentrations for both surface and ground water did not exceed the acute and chronic (non-cancer) DWLOCs. **However, the 36 year annual mean triallate residue concentration in surface water exceeded the DWLOC for cancer (0.45 ppb).**

Therefore, Tier II PRZM-EXAMS modeling with the index reservoir (IR) and the PCA (Percent Crop Correction Factor) was conducted to refine the Tier 1 water assessment (Memo, J. Hetrick et. al., 12/22/99). When using this model, the estimate should be higher than most values that are seen in areas where a particular crop is grown. A preliminary assessment comparing monitoring data for a few chemicals to estimates made using these methods indicate the estimate may not be consistently conservative. However, monitoring data at drinking water facilities is sparsely available and we are unable to check the validity for most crops against monitoring data at this time.

The index reservoir represents a watershed that is more vulnerable than most used as drinking water sources. It was developed from a real watershed in western Illinois (Jones et al., 1997). The index reservoir is used as a standard watershed that is combined with local soils, weather, and cropping practices to represent a vulnerable watershed for each crop that could support a drinking water supply.

A single steady flow has been used to represent the flow through the reservoir. Discharge from the reservoir also removes chemical from it so this assumption will underestimate removal from the reservoir during wet periods and overestimates removal during dry periods. This assumption can both underestimate or overestimate the concentration in the reservoir depending upon the annual precipitation pattern at the site. The index reservoir scenario uses the characteristic of a single soil to represent all soils in the basin. Soils can vary substantially across even small areas, thus, this variation is not reflected in these simulations.

The index reservoir scenario does not consider tile drainage. Areas that are prone to substantial runoff are often tile drained. This may underestimate exposure, particularly on a chronic basis (the watershed on which the IR is based had no documented tile drainage). Additionally, EXAMS is unable to easily model spring and fall turnover which would result in complete mixing of a chemical through the water column during these events. Because of this inability, Shipman City Lake has been simulated without stratification. There is data to suggest that Shipman City Lake does stratify in the deepest parts of the lake at least in some years. This may result in both an over and underestimation of the concentration in drinking water depending upon the time of the year and the depth the drinking water intake is drawing from. A full description of the Index Reservoir is provided in the *“Guidance for Use of the Index Reservoir in Drinking Water Exposure Assessment”* from EFED.

The PCA factor adjusts for the highest specific crop coverage on a 8 digit Hydrologic Unit Code (HUC) watershed (Effland et al., 1999). The PCA for wheat is 0.56. Limitations in the data used to develop the PCA include:

The size of the 8-digit HUC may not provide reasonable estimates of actual PCAs for smaller watershed capable of supporting a community water system.

The conversion of county-level data to watershed-based percent crop areas assume the distribution of the crops within a county is uniform and homogeneous. Distance between the treated fields and the water body is not addressed.

The PCA's were generated using 1992 Census of Agriculture. However, recent changes in the agriculture sector from farm bill legislation may significantly impact the distribution of crops throughout the country. Therefore, the approach assumes that year-to-year variation in cropping patterns are minimal, thus, have minimal impacts.

Although surface water monitoring data from non-targeted studies indicate that time weighted mean triallate (parent only) concentrations do not exceed the DWLOC for cancer (0.45 ppb), there are no surface water monitoring data available to assess TCPSA concentrations in surface waters.

4.2.2.a. Surface Water Modeling

Tier II modeling was conducted using PRZM (ver. 3.1) and EXAMS (ver 2.97.5) using IR and PCA. Tables 20 and 21 summarize the cumulative triallate residues (triallate + TCPSA) concentrations from spring application on spring wheat and fall applications on winter wheat, respectively. Shallow incorporation elevates the triallate concentrations in surface waters. However, the main factor affecting triallate runoff appears to be dependent on application date; spring applications of triallate regardless of incorporation depth caused annual mean triallate residue concentration to exceed the chronic cancer DWLOC of 0.45 ppb (see Section 4.2.2d. for DWLOC calculations).

Table 20. Triallate Residue Concentration (µg, triallate equivalents/L) in Surface Water for Spring Wheat in North Dakota (IR + PCA)

Concentration	Triallate		TCPSA		Cumulative Triallate Residues ²	
	2" incorporation	No incorporation	2" incorporation	No incorporation	2" incorporation	No incorporation
Peak ¹	3.452	7.764	0.777	1.688	4.229	9.452
90 Day Average ¹	1.690	3.731	0.624	1.357	2.314	5.088
Annual Mean	0.642	1.421	0.310	0.675	0.952	2.096
36 Year Annual Mean	0.391	0.875	0.175	0.382	0.566	1.257

1-1 in 10 year concentration

2-Summation of triallate and TCPSA

Table 21. Triallate Residue Concentration (µg, triallate equivalents/L) in Surface Water for Winter Wheat in North Dakota (IR + PCA)

Concentration	Triallate		TCPSA		Cumulative Triallate Residues [*]	
	2" incorporation	No incorporation	2" incorporation	No incorporation	2" incorporation	No incorporation
1/10 Peak	3.11	6.83	1.11	2.41	4.22	9.24
1/10 90 Day Average	1.30	2.87	0.91	1.98	2.21	4.85
1/10 Annual Mean	0.39	0.87	0.43	0.95	0.82	1.82

Table 21. Triallate Residue Concentration (µg. triallate equivalents/L) in Surface Water for Winter Wheat in North Dakota (IR + PCA)

36 Year Annual Mean	0.15	0.35	0.21	0.46	0.36	0.81
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* Summation of triallate and TCPSA

4.2.2.b. Ground Water Modeling

The environmental fate data for triallate suggest it is not expected to move into ground water. This assessment is based on triallate's moderate soil sorption affinity (K_{oc}) and its low to moderate persistence in terrestrial environment. In contrast, TCPSA has fate properties of pesticides (low K_{oc} and moderate persistence) found in groundwater.

Based on the SCI-GROW model, estimated concentrations of triallate residues (triallate + TCPSA) in shallow ground water are not expected to exceed 0.21 ppb (Table 22). This concentration can be considered as both the acute and chronic value.

SCI-GROW, the model used for estimating the ground-water environmental concentration is a screening level model developed by Dr. Michael Barrett of EPA/OPP to estimate the maximum ground-water concentration from the application of a pesticide to crops. As such, the estimated maximum concentration derived using SCI-GROW should be considered a high-end to bounding estimate of acute exposure. If the risk associated with this estimate is exceeded, either at the acute or chronic endpoints, refinement of the exposure estimate will be necessary to better characterize actual exposures.

Table 22. SCI-GROW Triallate Residue Concentrations (µg. triallate equivalents/L [ppb]) in Groundwater

Crop	Triallate	TCPSA	Cumulative Triallate Residues ¹
Winter Wheat	0.03	0.18	0.21
Spring Wheat	0.02	0.15	0.17

1-Summation of triallate and TCPSA

4.2.2.c. Monitoring Data

a. Ground Water

There have been no detections of triallate in ground water monitoring studies including NAWQA and STORET. Triallate also was not reported in the EPA Pesticide in Ground Water Database.

Environmental fate data for triallate suggest that triallate is not expected to move into groundwater because it has moderately high sorption affinity to soil (low mobility) and low to moderate persistence. In contrast, TCPSA has fate properties of pesticides (low K_{oc} and moderate persistence) found in groundwater. There are no ground water monitoring data for TCPSA to assess leaching potential under actual use conditions.

b. Surface Water

Surface water monitoring data indicate the frequency and magnitude of triallate detections in surface water are associated with small grain production areas in the northern tier states of United States (e.g. Minnesota to Washington) and Canadian Prairie Provinces. In the United States, the highest detection frequency (50% of samples) and concentration of triallate (0.65 µg/L) were found in filtered, ambient water samples in the Northern Red River Basin and the Central Plateau of the Columbia River USGS NAWQA study units. The maximum annual peak and maximum time weighted annual mean triallate concentration, respectively, were 0.28 and 0.0775 µg/L for the Northern Red River Basin and 0.65 and 0.0478 µg/L for the Central Plateau of the Columbia River. In Canadian monitoring programs, the maximum triallate concentration in unfiltered water was 0.87 µg/L from a farm pond. A higher triallate concentration (102.6 µg/L) was observed in a single sample (# 876274, 10/1/87) in a Canadian Prairie Surface Water study in the Qu'Appelle River. However, further analysis of this detection indicates an error in the reported data ; the correct concentration is 0.0026 µg/L (FAX, Bing Chu to Dr. Andrew Klien, Monsanto, 2/20/98). Long-term average concentrations (e.g., time-weighted annual mean) could not be determined from Canadian monitoring studies. EFED notes that only peak triallate concentrations in the reported monitoring studies exceed the HED cancer DWLOC. However, the maximum time-weighted annual mean concentration of triallate (0.077 µg/L) is substantially lower than the HED cancer DWLOC (0.45 µg/L).

Based on the water assessment for triallate and its degradate TCPSA, EFED believes that the major uncertainty in the water assessment is related to the fate and transport of TCPSA. EFED recommends that the registrant submit Subdivision N guideline studies for TCPSA including aerobic soil metabolism, aerobic aquatic metabolism, and batch equilibrium. These data are needed to confirm the supplemental data used in modeling. EFED notes that the registrant is attempting to fill data gaps for TCPSA water assessment by preparing a surface water monitoring program at community water systems in the triallate use areas. Such a monitoring program would provide the necessary data to assess triallate and TCPSA concentrations in drinking water.

4.2.2.d. Drinking Water Risk (Acute, Chronic, and Cancer)

Drinking water levels of comparison (DWLOCs) for acute, chronic, and cancer dietary risk from drinking water were calculated. A DWLOC is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. The Agency uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. They do have an indirect regulatory impact through aggregate exposure and risk assessments.

HED has calculated DWLOCs for acute and chronic (non-cancer and cancer) exposure to triallate + TCPSA in surface and ground water for the U.S. population, children (1-6 yrs), and females (13+/-nursing). DWLOCs were calculated and compared to model estimates of triallate concentrations in ground and surface water. Based on the acute and chronic dietary exposure estimates presented above, drinking water levels of comparison (DWLOCs) were calculated using the formulas presented below.

$$DWLOC_{acute} (F g/L) = \frac{[acute\ water\ exposure\ (mg/kg/day) \times (body\ weight,\ kg)]}{[consumption\ (L/day) \times 10^{-3}\ mg/F\ g]}$$

where acute water exposure (mg/kg/day) = aPAD - acute food exposure (mg/kg/day)

$$DWLOC_{chronic} (F g/L) = \frac{[chronic\ water\ exposure\ (mg/kg/day) \times (body\ weight,\ kg)]}{[consumption\ (L/day) \times 10^{-3}\ mg/F\ g]}$$

where chronic water exposure (mg/kg/day) = [cPAD - (chronic food exposure + residential exposure) (mg/kg/day)]

For Cancer DWLOCs:

$$DWLOC_{cancer} (ug/L) = \frac{[chronic\ water\ exposure\ (mg/kg/day) \times (body\ weight)]}{[consumption\ (L) \times 10^{g3}\ mg/ug]}$$

$$chronic\ water\ exposure\ (mg/kg/day) = \frac{Negligible\ risk}{Q^c} \& [(chronic\ food \% residential\ exposure)\ (mg/kg/day)]$$

The default body weights and drinking water consumption used were: 2 liters (L) of drinking water consumed per day by adults and 1 L per day consumed by children; and for default body weights: males - 70kg, females - 60kg, and children - 10 kg. The negligible risk is 1×10^{-6} . DWLOCs are shown in Tables 23 to 25.

Table 23. Acute Scenario

Subgroup	NOAEL (mg/kg/day)	Acute PAD (mg/kg/day)	Food Exposure (from DEEM™) (mg/kg/day)	Water Exposure (mg/kg)	SCI- GROW (ppb)	PRZM/ EXAMs (ppb)		DWLO C (ppb)
						2" Incorporatio n	No Incorporatio n	
U.S. Population	60	0.60	0.000268	0.599732	0.21	4.229	9.452	20,990
Children (1-6 years)	60	0.60	0.000650	0.599350	0.21	4.229	9.452	6000
Females (13+ nursing)	5	0.017	0.000305	0.016695	0.21	4.229	9.452	500

Table 24. Chronic DWLOCs

Subpopulation	Food Exposure (from DEEM™) mg/kg/day)	Chronic PAD mg/kg/day	Maximum Water Exposure (mg/kg)	SCI-GROW (ppb)	PRZM /EXAMs (ppb)		DWLOC (ppb)
					2" Incorporation	No Incorporation	
U.S. Population	0.000001	0.025	0.024999	0.21	0.566	1.257	875
Females (13+ yrs/nursing)	0.000002	0.025	0.024998	0.21	0.566	1.257	750
Children (1-6 years old)	0.000003	0.025	0.024997	0.21	0.566	1.257	250

Table 25. Cancer DWLOC

Subgroup	Q ₁ * (mg/kg/day) ¹	Food Exposure (from DEEM™) (mg/kg/day)	Water Exposure (mg/kg)	SCI- GROW (ppb)	PRZM/ EXAMS (ppb)		DWLOC (ppb)
					2" incorporation	No incorporation	
U.S. population	0.0717	0.000001	0.00001	0.21	0.566	1.257	0.45

Estimated maximum concentrations of triallate + TCPSA in surface water are 4.229 ppb (2" incorporation) and 9.452 ppb (no incorporation). The estimated average concentration of triallate (+ TCPSA) in surface water is 0.566 ppb (mean annual with 2" incorporation) and 1.257 ppb (mean annual with no incorporation). Concentrations in ground water are not expected to be higher than 0.21 ppb. Note: For the purposes of the screening-level assessment, the maximum and average concentrations in ground water are not believed to vary significantly. The maximum estimated concentrations of triallate +TCPSA in surface water are less than OPP's DWLOCs for triallate +TCPSA in drinking water as a contribution to acute and chronic (non-cancer) aggregate exposure. **However, the 36 year annual mean estimated concentrations exceed OPP's DWLOC for triallate +TCPSA in drinking water as a contribution to cancer aggregate exposure.**

4.3 Occupational Exposure

Triallate is a thiocarbamate herbicide that is used to control wild oats in peas, lentils, barley, durum wheat, spring and winter wheat, and triticale, and for suppression of downy brome (*Bromus tectorum*), Cheat (*Bromus secalinus*) and Japanese brome (*Bromus japonicus*) in winter wheat and winter barley. Triallate is formulated as a technical-grade manufacturing product (94.0 percent active ingredient), granular (10.0 percent active ingredient), a combination granule named BUCKEL® (10 percent Triallate active ingredient and 3 percent %,%-triflouro-2,6 dinitro-N,N-dipropyl-p-toluidine), and emulsifiable concentrate (46.3 percent active ingredient). There has been relatively few incidents of illness reported due to triallate use. On the list of the top 200 chemicals for which the National Pesticide Telecommunications Network received calls from 1984-1991, triallate was not reported to be involved in human incidents.

Triallate can be applied with a groundboom, tractor- drawn spreader, or an enclosed fixed- wing - aircraft, at a rate of 1.00 to 1.5 quarts active ingredient (a.i.) per acre for liquid and 1.25 to 1.5 pounds a.i. per acre for granules. Aircraft application is banned for BUCKEL®, due to presence of %,%-triflouro-2,6-dinitro-N,N-dipropyl-p-toluidine which is the other active ingredient in BUCKEL®. Aerial application of granular formulations is about 1 percent of total use.

Based on the handlers activity use pattern the duration of exposure is only short-term (1-7 days) and intermediate-term (1 week to 6 months) for occupational handlers. This is based on the fact that there are different planting periods of the registered crops for triallate. Based on the current use pattern (Maximum application rate of 1.5 lb (a.i.) /A per year) and handler activities, long-term (chronic) exposure is not anticipated (nor expected); therefore, a dose and end point was not identified by HIARC nor is a long-term (chronic) exposure risk assessment required.

The Pesticide Handler Exposure Database (PHED) was used because there is no chemical specific data, which reflects the actual use patterns for this herbicide. When using PHED as a tool for estimating exposure, high confidence data have a grade quality of A or B and a minimum of 15 replicates per body part. Low confidence data are based on D or E grade data and/or fewer than 15 replicates per body part. Mixing/loading and applying liquids for groundboom scenario(s) have **high quality** grade data. Mixing/loading liquids in support of enclosed fixed wing-aircraft have **high quality** grade data, and applying liquids for an enclosed fixed wing- aircraft scenario have **medium quality** grade data. Mixing/loading granulars in support of an enclosed fixed wing-aircraft, and tractor

drawn broadcast spreader scenario(s) have **low quality grade data** for dermal data points but **has high quality data** for inhalation data points. Applying granulars for aerial and tractor drawn broadcast spreader scenario(s) have low quality grade data.

There is minimal potential for triallate exposure via inhalation because of the low acute toxicity ($LC_{50} > 5.3$ mg/L, Toxicity Category IV), low vapor pressure (16mPa at 25° C, for the technical grade) and low unit exposure values of daily inhalation doses at the baseline. However, occupational inhalation daily dose values were still calculated and presented for this risk assessment. Occupational inhalation exposures were not considered to have significant effects on this risk assessment. At baseline [and at engineering controls for scenarios; 3(b) and 4(b) - fixed wing enclosed aircraft] inhalation, calculated short-, and intermediate-term MOEs **ranged between 330 to 8,400 which are greater than the target MOE of 100; which does not exceed HED's level of concern.**

For occupational handlers, dermal MOE(s) above 100 do not exceed HED's level of concern. All occupational exposure risk estimates, for Far-Go® (Granular and Liquid) formulation for short- and intermediate-term exposures for handlers, do not exceed HED's level of concern at baseline protection and enclosed fixed wing-aircraft scenarios (calculated dermal MOE's for mixer/loaders are > 6,800, for applicators, and flaggers are > 5000), **except for scenarios; 1a** [Mixing/loading liquids for ground boom application (MOE=86)], **and 1b** [Mixing/loading liquids for aerial application (MOE=20)]; **however with additional PPE (gloves) to minimize dermal exposures for these two scenarios, exposure risk estimates, do not exceed HED's level of concern (MOEs are above 2500).**

Cancer risk estimates at baseline protection (i.e., long-sleeve shirt, long pants, no gloves, shoes, and socks) **do not exceed 4.0×10^{-5} , except for (1a)**[mixing/loading liquids] in support of groundboom, **(1b)** [mixing/loading liquids], **and (2a)** [loading granules] in support of aerial application; **however, with implementing risk mitigation [additional PPE; gloves] to minimize dermal exposures cancer risk estimates do not exceed 7.7×10^{-5} .**

For pre-emergent herbicides used on crops that are mechanically planted, such as peas, lentils, barley, durum wheat, spring and winter wheat, a post-application exposure assessment is not necessary unless the exposure assessor has specific informational data regarding the application method and timing, or the crop and cultural practices (per Exposure Scientific Advisory Committee (SAC) policy #8). Based on triallate registered use patterns, a post-application exposure assessment is not required.

There are no residential uses nor are there any occupational uses resulting in non-dietary exposure to infants and children, at this time.

4.3.1 Handler Exposures & Assumptions

Based on the use patterns, *it is not expected that one handler would mix, load and apply (M/L/A) Triallate to an entire farm's acreage or farms' acreage.* A handler would mix/load or either apply Triallate; therefore all scenarios have reflected these use activity patterns. EPA has identified ten Triallate exposure scenarios for occupational handlers: (1a) mixing/loading liquids for groundboom application; (1b) mixing/loading liquids for aerial application; (2a) mixing/loading granules for aerial application; (2b) mixing /loading granules for tractor drawn /mechanical spreader application; (3a) applying liquid with groundboom sprayer; (3b) applying liquid with an

enclosed fixed-wing- aircraft; (4a) applying granules by an enclosed fixed-wing-aircraft ; (4b) applying granules with tractor drawn sprayer;(5) flagging for liquid application;(6) flagging for granular application.

Dermal and inhalation exposures (developed using PHED Version 1.1 surrogate data⁶ because there are no chemical-specific data) are presented in Table 26. Table 27 presents the risk assessment for short- and intermediate-term dermal and inhalation exposures at baseline attire. PHED is a generic database that estimates unit exposure based on the theory that physical parameters (e.g. the type of PPE worn, method of application, cab type, mixing/loading scenario, formulation) rather than chemical properties are the determinant factors of exposure analysis. When using PHED as a tool for estimating exposure, high confidence data have a grade quality of A or B and a minimum of 15 replicates per body part. Low confidence data are based on D or E grade data **and/or fewer than 15 replicates per body part**. Table 28 presents the risk assessment for short- and intermediate-term dermal exposures with additional personal protective equipment(PPE). Table 29 presents the risk for short- and intermediate-term occupational handler with engineering controls. Table 30 summarizes the caveats and parameters specific to each exposure scenario and corresponding risk assessment. Table 31 summarizes the cancer risks for the various exposure scenarios.

The following assumptions are made in the exposure calculations:

- Average body weight of a female adult handler (60) kg is used, because the dose for risk assessment was derived from a developmental study (i.e, Pregnant females were the test animals)
- A typical workday is 8-hour long.
- Calculations of handler exposures are completed using the maximum application rates recommended by the available Triallate labels.
- Unit exposure values using generic data from the Pesticide Handler Exposure Database (PHED). When generic data were not available to represent various risk mitigation options (i.e., the use of PPE) for a particular scenario, protection factors were applied. The details for each scenario are discussed in Table 30.
- Area treated in each scenario: 80 acres for groundboom and tractor-drawn spreader application; 350 acres for application with fixed-wing-aircraft.
- Aerial application in this assessment is assumed to be by fixed-wing-aircraft only (Exposure SAC Policy#6).
- Exposure frequency for private farmers applicator = 15days
- Exposure frequency for commercial applicator = 30 days
- Exposure frequency is 35 years
- Life time is considered to be 70 years

Note: EXPOSURE SAC Policy #006: Only enclosed fixed wing-aircraft scenario risk estimates were assessed, because of the insufficient number of data points for fixed-wing, open-cockpit aircraft in the PHED, these data should not be used either as a subset, or in combination with data from fixed-wing, closed-cockpit aircraft. Exposure from open-cockpit planes is considered qualitatively to present a potentially greater exposure to applicators than closed-cockpit, but the quantitative extent remains a data gap until empirical data are generated. If the estimated MOE for application of a given pesticide using closed-cockpit data from PHED or a pesticide-specific exposure study is an order of magnitude larger (**at least 1000 for triallate**) than the uncertainty factor (i.e., the target MOE), then the use of an open-cockpit fixed-wing aircraft for application also should be acceptable. The enclosed fixed wing-aircraft scenario risk

estimates are below 1000; therefore an open-cockpit is not acceptable [aggregate risk estimate was done for 4b, because it is the smallest daily dose for enclosed fixed wing-aircraft ({dermal+inhalation = 1.12 X10⁻² mg/kg/day}); MOE = 450]

Potential dermal and inhalation daily exposures for occupational handlers were calculated using the following formulas (1.0 percent dermal absorption was assumed):

$$\text{Daily Inhalation Exposure} \left(\frac{\text{mg ai}}{\text{day}} \right) = \text{Unit Exposure} \left(\frac{\text{Fg ai}}{\text{lb ai}} \right) \times \text{Conversion Factor} \left(\frac{1\text{mg}}{1,000 \text{ Fg}} \right) \times \text{Use Rate} \left(\frac{\text{lb ai}}{\text{A}} \right) \times \text{Daily Acres Treated} \left(\frac{\text{A}}{\text{day}} \right)$$

$$\text{Daily Dermal Exposure} \left(\frac{\text{mg ai}}{\text{day}} \right) = \text{Unit Exposure} \left(\frac{\text{mg ai}}{\text{lb ai}} \right) \times \text{Use Rate} \left(\frac{\text{lb ai}}{\text{A}} \right) \times \text{Daily Acres Treated} \left(\frac{\text{A}}{\text{day}} \right)$$

The inhalation and dermal daily doses were calculated using the following formulas:

$$\text{Daily Inhalation Dose} \left(\frac{\text{mg ai}}{\text{kg/day}} \right) = \text{Daily Inhalation Exposure} \left(\frac{\text{mg ai}}{\text{day}} \right) \times \left(\frac{1}{\text{Body Weight (kg)}} \right) (1 \text{ (100\% Inhalation absorption)})$$

$$\text{Daily Dermal Dose} \left(\frac{\text{mg ai}}{\text{kg/Day}} \right) = \text{Daily Dermal Exposure} \left(\frac{\text{mg ai}}{\text{Day}} \right) \times \left(\frac{1}{\text{Body Weight (kg)}} \right) (0.01 \text{ (1\% Dermal absorption)})$$

* The estimated dermal absorption value of 1% and the estimated inhalation absorption value of 100% were determined by the HIARC and obtained by dividing the LOAEL of 30.0 mg/kg/day (based on decrease in body weight from the rat oral developmental study) by the LOAEL of 3000.0 mg/kg/day (from the 21-day dermal rat study).

4.3.2 Post-Occupational Application Exposure Assessments

No DFR (Dislodgeable Foliar Residue) data or exposure monitoring data were submitted for Triallate. However, HED believes that the potential for post-application worker exposure is low, provided the 12 hour restricted entry interval is observed. There is low potential for exposure due to the timing of applications. Triallate is applied to the soil and/or soil incorporated pre-emergence for wheat, barley, peas, and lentils. This is well before the plants are mature, which likely mitigates the potential for post-application exposure due to contact with treated

foliage. Additionally, most agricultural operations for wheat, barley, peas, and lentils are mechanically harvested which minimizes the potential for contact. **Significant exposure to Triallate during mechanical planting, harvesting, or any other late season activities, is not likely since** Triallate is applied pre-emergent (per Exposure Scientific Advisory Committee (SAC) policy #8). Also significant exposure to Triallate during scouting, or while handling or coming in contact with treated soil is minimum (less than or equal to the amount of exposure that occurs in the application of triallate; which did not exceed HED's level of concern), and would not exceed HED's level of concern. **Therefore, HED does not require that any Post-application exposure data be generated to support the reregistration of Triallate.**

4.3.3 Risk Calculations

For Triallate, the NOAEL for short and intermediate- term is 5 mg/kg/day for both dermal and inhalation exposure. This value was used to calculate short and intermediate-term MOEs.

Short- term and, intermeiate-term MOEs were calculated as follows:

$$MOE = \frac{NOAEL \left(\frac{mg}{kg/day} \right)}{Daily \ Dermal \ Dose \left(\frac{mg}{kg/day} \right)}$$

$$MOE = \frac{NOAEL \left(\frac{mg}{kg/day} \right)}{Daily \ Inhalation \ Dose \left(\frac{mg}{kg/day} \right)}$$

Short-term and intermediate -term

Dermal MOEs for different scenarios were obtained and risks calculated using the short-term and intermediate-term NOAEL of 5.0 mg/kg/day. The target MOE was assumed to be 100.

- The calculations based on dermal an inhalation exposure indicate that the MOEs are more than 100 at **baseline protection and enclosed fixed wing-aircraft scenarios** except for the dermal exposure of the following scenarios:
- 1a) Mixing/loading liquids for ground boom application (MOE=86).

- 1b) Mixing/loading liquids for aerial application (MOE=20).
- **Additional Personal Protective Equipment (PPE)** are used to minimize dermal exposure for scenarios; 1(a) (mixing/loading liquid, supporting ground boom), & 1(b) (mixing/loading liquid, supporting aerial). The only addition of PPE is gloves. All calculated handler (dermal) exposures indicate **that all MOEs are now above 100.**
- Due to low unit exposure values of daily inhalation doses at the baseline, occupational inhalation exposures were not considered to have significant effects on this risk assessment. However, occupational inhalation daily dose values were still calculated and presented for this risk assessment. At baseline [and at engineering controls for scenarios; 3(b) and 4(b) - enclosed fixed wing-aircraft] inhalation, calculated short-, and intermediate-term MOEs **ranged between 330 to 8,400 which are larger than the target MOE of 100; which does not exceed HED's level of concern.**

Exposure assessment risk estimates were only conducted for enclosed fixed wing-aircraft, see section 4.3.1, Handler Exposures and Assumptions for rationale. Therefore a restriction should be put on the label, that only allow for enclosed fixed wing-aircraft applications.

• **Aggregate Occupational Handler Exposure Risks**

- For occupational handlers, MOE(s) above 100 do not exceed HED's level of concern. All occupational exposure aggregate (dermal+inhalation) risk estimates, for Far-Go[®] (Granular and Liquid) formulation for short- and intermediate-term exposures, **do not exceed HED's level of concern at the baseline protection and enclosed fixed wing-aircraft scenarios** [a range finding risk estimate was calculated, of the smallest aggregate daily dose (scenario 2a = {dermal + inhalation} = 1.574×10^{-2} mg/kg/day); which calculated a MOE = 320], **except for scenarios; 1a) and 1b); however with additional PPE (gloves) to minimize dermal exposures for these two scenarios, exposure risk estimates, do not exceed HED's level of concern** [a range finding risk estimate was also calculated, of the smallest aggregate daily dose (scenario 1b = {dermal + inhalation} = 1.25×10^{-2} mg/kg/day); which calculated a MOE = 400].
- Based on the current use pattern (Maximum application rate of 1.5 lb (a.i.) /A per year), *long-term dermal exposure is not anticipated*; therefore, a dose and end point was not identified. Long-term (chronic) dermal exposures are not expected as a result of the application frequency, hence a chronic exposure risk assessment is not required.

• **Cancer Risks**

EPA conducted an assessment of the carcinogenic risk estimates associated with Triallate following exposures to occupational handlers. The cancer risks, for the handler (dermal plus inhalation) exposures, are based on the assumption that a private farmer applies Triallate products, 15 times a year (Fall, Spring), and a commercial applicator applies Triallate products to 10 farms, 30 times a year (Fall, Spring). The calculations indicate that the **cancer risk estimates at baseline protection** (i.e., long-sleeve shirt, long pants, no gloves, shoes, and socks) **do**

not exceed 4.0×10^{-5} , except for (1a)[mixing/loading liquids] in support of groundboom, **(1b)** [mixing/loading liquids], **and (2a)** [loading granules] in support of aerial application; **however, with implementing risk mitigation [additional PPE; gloves]to minimize dermal exposures cancer risk estimates do not exceed 7.7×10^{-5} .**

Table 26: Occupational Handler Short- and Intermediate-term Dermal and Inhalation Exposures to Triallate						
Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai) ^a	Baseline Inhalation Unit Exposure (µg/lb ai) ^b	Maximum Application Rates (lb ai/acre) ^c	Daily Acres treated ^d	Daily Dermal Exposure (mg/day) ^e	Daily Inhalation Exposure (mg/day) ^f
Mixer/Loader Exposure						
Mixing/loading liquids for ground boom application (1a)	2.9	1.2	1.5	80	348	0.144
Mixing/loading liquids for aerial application (1b)				350	1523	0.63
Mixing/loading granules for aerial application (2a)	0.0084	1.7		350	4.41	0.890
Mixing/loading granules for tractor drawn/mechanical spreader application (2b)	0.0084	1.7		80	1.01	0.204
Applicator Exposure						
Applying liquids with a ground boom sprayer (3a)	0.014	0.74	1.5	80	1.68	0.089
Applying liquids with enclosed cab fix-wing Aircraft (3b)	See Eng. Control	See Eng. Control		See Eng. Control	See Eng. Control	See Eng. Control
Applying granules with tractor-drawn sprayer (4a)	0.0099	1.2		80	1.19	0.144
Applying granules with enclosed fixed-wing Aircraft (4b)	See Eng. Control	See Eng. Control		See Eng. Control	See Eng. Control	See Eng. Control
Flagger Exposure						
Flagging for liquid application(5)	0.011	0.35	1.5	350	5.78	0.184
Flagging for granules application(6)	0.003	0.15		350	1.58	0.079

^a Baseline dermal unit exposure represents long pants, long sleeved shirt, **no gloves**, open mixing/loading, open cab tractor.

^b Baseline inhalation exposure represents no respirator.

^c Application rates are maximum rate values found on Triallate labels.

^d Daily acres treated values are from the EPA HED estimates of acreage in a single day for each exposure scenario of concern.

^e Daily dermal exposure (mg/day) = Unit Exposure (mg/lb ai) * Appl. rate (lb ai/acre) * Acres treated (acres/day).

^f Daily inhalation exposure (mg/day) = Unit Exposure (µg/lb ai) * (1mg/1000 µg) Conversion * Application Rate (lb ai/A) * Acres treated (acres/day).

Table 27. Occupational Handler Short-term and Intermediate-term Risks from Triallate at Baseline

Exposure Scenario (Scenario #)	Baseline Dermal			Baseline Inhalation	
	Daily Dose (mg/kg/day) ^a	Short-term MOE ^b	Intermediate-term MOE ^c	Daily Dose (mg/kg/day) ^d	Short- & Interm.term MOE ^e
Mixer/Loader Exposure					
Mixing/loading liquids for ground boom application (1a)	5.80e-02	86	86	2.40e-03	2100
Mixing/loading liquids for aerial application (1b)	2.54e-01	20	20	1.05e-02	480
Mixing/loading granules for aerial application (2a)	7.40e-04	6800	6800	1.50e-02	340
Mixing/loading granules for tractor drawn application (2b)	1.70e-04	29000	29000	3.00e-03	1500
Applicator Exposure					
Applying liquids with a ground boom sprayer (3a)	2.80e-04	18000	18000	1.50e-03	3400
Applying liquids with enclosed fix-wing aircraft (3b)	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control
Applying granules with tractor-drawn spreader(4a)	2.00e-04	25000	25000	2.30e-03	2100
Applying granules with enclosed fixed-wing aircraft(4b)	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control
Flagger Exposure					
Flagging for liquid application(5)	9.60e-04	5000	5000	3.10e-03	1700
Flagging for granules application(6)	2.60e-04	19000	19000	1.30e-03	3800

^a Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day) * 0.01 dermal absorption / Body weight(60 kg).

^b Short-term Dermal MOE = NOAEL (5 mg/kg/day) / Daily Dermal Dose (mg/kg/day).

^c Intermediate-term Dermal MOE = NOAEL (5 mg/kg/day) / Daily Dermal Dose (mg/kg/day).MOEs have been rounded to 2 significant figures(Exposure Sac Policy #1).

^d Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day) / Body weight (60 kg). MOEs have been rounded to 2 significant figures (Exposure Sac Policy #1).

^e Short term inhalation MOE = NOAEL (5 mg/kg/day) / Daily inhalation Dose (mg/kg/day)

Table 28. Occupational Handler Short-term and Intermediate-term Risks from Triallate with Additional PPE				
Exposure Scenario (Scenario #)	Dermal-Additional PPE			
	Unit Exposure (mg/lb ai handled) ^a	Daily Dose(mg/kg/day) ^b	Short-term MOE ^c	Int-term MOE ^d
Mixer/Loader Exposure				
Mixing/loading liquids for ground boom application (1a)	0.023	4.60e-04	11000	11000
Mixing/loading liquids for aerial application (1b)		2.00e-03	2500	2500

^a Additional PPE for all scenarios includes long pants, long sleeved shirt, and **gloves** (90% protection factor for chemical resistance gloves).

^b Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day) * 0.01 dermal absorption/ Body weight (60 kg).

^c Short-term Dermal MOE = NOAEL (5 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).MOEs have been rounded to 2 significant figures (Exposure Sac Policy #1)

^d Intermediate-term Dermal MOE = NOAEL (5 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).MOEs have been rounded to 2 significant figures (Exposure Sac Policy #1)

Table 29. Occupational Handler Short-term ,and Intermediate-term Risks from Triallate with Engineering Control					
Exposure Scenario (Scenario #)	Unit Exposure (mg/lb ai) ^a	Dermal Daily Dose ^b	Inhalation Daily Dose ^b	Short-term MOE ^c Derm/Inhal.	Int-term MOE ^d Derm/Inhal.
Applicator Exposure					
Applying liquids with a groundboom sprayer (3a)	NA	NA	NA	NA	NA
Applying liquids with enclosed fix-wing aircraft. (3b)	0.0050	4.40e-04	6.00e-04	11000/8300	11000/8300
Applying granules with tractor-drawn spreader(4a)	NA	NA	NA	NA	NA
Applying granules with enclosed fixed-wing aircraft(4b)	0.0017	1.50e-04	1.10e-02	33000/450	33000/450

^a All scenarios include baseline PPE = long pants, long sleeved shirt, shoes and socks, and **no gloves**

^b Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day) * 0.01 dermal absorption/ Body weight (60 kg).

Daily Inhalation Dose (mg/kg/day) =Daily Inhalation Exposure (mg/day) * 1 (100%) Inhalation absorption/ Body weight (60 kg).

^c Dermal; Inhalation, Short-term MOE = NOAEL (5 mg/kg/day)/ Daily (Dermal or Inhalation) Dose (mg/kg/day). MOEs have been rounded to 2 significant figures (Exposure Sac Policy #1)

^d Dermal; Inhalation, Intermediate-term Dermal MOE = NOAEL (5 mg/kg/day)/ Daily (Dermal or Inhalation) Dose (mg/kg/day). MOEs have been rounded to 2 significant figures (Exposure Sac Policy #1)

NA= calculated MOE's are adequate (above 100)

Table 30. Exposure Scenario Descriptions for the Use of Triallate			
Exposure Scenario #	Data Source	Standard ^a assumptions (8-hr work day)	Comments ^b
Mixer/Loader Descriptors			
Mixing/Loading Liquid Formulations(1a,1b)	PHED V1.1	80 acres (ground boom), 350acres (aerial)	Baseline: Hand, dermal, and inhalation data are AB grades. Hand = 72 to 122 replicates; dermal = 53 replicates; and inhalation = 85 replicates. High confidence in hand/dermal and inhalation data. No protection factor was needed to define the unit exposure value. PPE: The same dermal data are used as for the baseline coupled with additional use of chemical resistance gloves (90% protection factor). Hand data are AB grades, with 59 replicates. High confidence in hand/dermal data.
Mixing/Loading Granular formulations(2a,2b,)	PHED V1.1	80 acres (tractor- drawn), 350 acres (aerial)	Baseline: Dermal replicates = 33-78, ABC grade. Hands = 10 replicates; Low Confidence; and inhalation = 58 replicates, AB grade High confidence.
Applicator Exposure			
Applying liquid with a groundboom sprayer (3a)	PHED V1.1	80 acres	Baseline: Hand, dermal, and inhalation data are AB grades. Hand = 29 replicates; dermal = 23 to 42 replicates; and inhalation = 22 replicates. High confidence in hand/dermal and inhalation data. No protection factor was needed to define the unit exposure value.
Applying liquids with an enclosed fixed-wing Aircraft (3b)	PHED V1.1	350 acres	Eng.Control: Dermal replicates = 24 to 48, ABC grades. Hand replicates = 7, All Grades. Low Confidence run due to inadequate hand number and poor grade quality. Inhalation replicates = 23, ABC. Medium Confidence.
Applying Granules with a tractor-drawn sprayer (4a)	PHED V1.1	80 acres	Baseline: Hands ,dermal, and inhalation data are AB grades. Hand = 5 replicates, dermal = 1 to 5 replicates; and inhalation = 5 replicates. Low confidence in hand/dermal and in inhalation data. No protection factor was needed to define the unit exposure value.
Applying granules with an enclosed fixed wing- Aircraft (4b)	PHED V1.1	350 acres	Eng Control: Dermal replicates = 9 to 13, C grade. Hand replicates = 4, All Grades. Low Confidence run due to inadequate hand number and poor grade quality. Inhalation replicates = 13, All grades. Low Confidence.
Flagger Exposure			
Flagging for liquid application (5)	PHED V1.1	350 acres	Baseline: Hands, dermal and inhalation acceptable grades. Hands = 30 replicates; dermal = 18 to 28 replicates; and inhalation = 28 replicates. High confidence in dermal, hands, and inhalation data.
Flagging for granules application (6)	PHED V1.1	350 acres	Baseline: There are no data to estimate “single layer” or “gloved Exposure”. The only way to obtain a rough estimate is to apply 50% protection factor to “No Clothing” and 10% protection factor to “Single Layer No Gloves”.low Confidence Run. Inhalation exposure, 4 replicates, E grade. Low Confidence Run.

^a Standard Assumptions based on an 8-hour work day as estimated by HED. BEAD data were not available.

^b All handler exposure assessments in this document are based on the "Best Available" data as defined by HED SOP for meeting Subdivision U Guidelines. Best available grades are assigned to data as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality (i.e., All Grade Data) and number of replicates. High quality data with a protection factor take precedence over low quality data with no protection factor. Generic data confidence categories are assigned as follows:

High= grades A and B and 15 or more replicates per body part

Medium = grades A, B, and C and 15 or more replicates per body part

Low= grades A, B, C, D and E or any combination of grades with less than **15 replicates**

Table 31. Occupational Handler Short-term and intermediate -term Cancer(Q*) Risks for Triallate

Exposure Scenario #	Total Baseline Daily Dose ^a	Baseline LADD 15/30 ^b	Baseline Risk 15/30 ^c	PPE Total Daily Dose ^a	PPE LADD 15/30 ^b	PPE Risk 15/30 ^c	Eng. Cont. Total Daily Dose ^a	Eng LADD 15/30 ^b	Eng Risk 15/30 ^c
Mixer/Loader Exposure									
Mixing/loading liquids for ground boom application (1a)	5.18e-02	1.06E-3/ 2.13E-3	7.63E-5/ 1.53E-4	2.35e-03	4.83E-05/ 9.66E-05	3.46E-06/ 6.92E-06	2.90E-4	6.0E-6/ 1.2E-5	4.3E-7/ 8.5E-7
Mixing/loading liquids for aerial application (1b)	2.27e-01	4.66E-3/ 9.31E-3	3.34E-4/ 6.69E-4	1.03e-02	2.11E-04/ 4.22E-04	1.51E-05/ 3.0E-05	1.30E-3	2.6E-5/ 5.2E-5	1.85E-6/ 3.7E-6
Mixing/loading granules for aerial application (2a)	1.35e-02	2.75E-4/ 5.50E-4	1.97E-5/ 3.93E-5	1.30e-02	2.74E-4/ 5.48E-4	1.9E-5/ 3.8E-5	2.70E-4	5.5E-6/ 1.1E-5	3.95E-7/ 7.9E-7
Mixing/loading granules for tractor drawn application (2b)	3.10e-03	6.3E-5/ 1.26E-4	4.51E-6/ 9.01E-6	3.00e-03	6.1E-5/ 1.2E-4	4.4E-6/ 8.8E-6	6.10E-5	1.3E-6/ 2.5E-6	9.0E-8/ 1.8E-7
Application Exposure									
Applying liquids with a ground boom sprayer (3a)	1.53e-03	3.11E-5/ 6.20E-5	2.23E-6/ 4.51E-6	1.46e-03	2.99E-5/ 5.98E-5	2.15E-6/ 4.30E-6	1.60E-4	3.3E-6/ 6.6E-6	2.35E-7/ 4.7E-7
Applying liquids with enclosed fix-wing aircraft(3b)	ND	ND	ND	ND	ND	ND	8.91e-4	1.83E-5/ 3.66E-5	1.31E-6/ 2.63E-6
Applying granules with tractor-drawn spreader (4a)	2.23e-03	4.58E-5/ 9.19E-5	3.28E-6/ 6.56E-6	2.13e-03	4.38E-5/ 8.76E-5	3.14E-6/ 6.28E-6	4.10E-4	8.5E-6/ 1.7E-5	6.0E-7/ 1.2E-6
Applying granules with enclosed fixed-wing Aircraft(4b)	ND	ND	ND	ND	ND	ND	2.57e-4	5.28E-6/ 1.06E-5	3.79E-7/ 7.57E-7

Table 31. Occupational Handler Short-term and intermediate -term Cancer(Q*) Risks for Triallate

Exposure Scenario #	Total Baseline Daily Dose ^a	Baseline LADD 15/30 ^b	Baseline Risk 15/30 ^c	PPE Total Daily Dose ^a	PPE LADD 15/30 ^b	PPE Risk 15/30 ^c	Eng. Cont. Total Daily Dose ^a	Eng LADD 15/30 ^b	Eng Risk 15/30 ^c
Flagging for liquid application(5)	3.48e-03	7.10E-5/ 1.43E-4	5.11E-6/ 1.03E-5	NF	NF	NF	2.64e-03	5.43E-5/ 1.09E-4	3.89E-6/ 7.78E-6
Flagging for granules application(6)	1.34e-03	2.78E-5/ 5.57E-5	1.97E-6/ 3.95E-6	NF	NF	NF	1.13e-03	2.32E-5/ 4.64E-5	1.66E-6/ 3.32E-6

^a Baseline, PPE, or Eng. Control; Total (Dermal + Inhalation) Daily Dose (mg/kg/day) = Total [(Dermal * 0.01) + (Inhalation*1)] exposure (mg/day) dermal absorption/ Body weight (70kg) See Table 2 for dermal exposure.

^b Baseline, PPE, or Eng. Control; LADD (mg/kg/day) = Total (Dermal + Inhalation) Daily Dose (mg/kg/day) * (15 days (private farmers) OR 30days (commercial applicators) per year worked/ 365 days per year)*(35 years worked/ 70years life time).

^c Baseline, PPE, or Eng. Control; Risk = Baseline, PPE, or Eng. Control; LADD (mg/kg/day)* (Q₁). Where Q₁* = 7.17x10⁻² (mg/kg/day)⁻¹ Risk calculated for 15 days (private farmers) OR 30 days (commercial applicators) per year worked/ 365 days per year)*(35 years worked/ 70years life time).

Baseline dermal risk represents long pants, long sleeved shirt, **no gloves**, open mixing/loading, open cab tractor.

Maximum PPE for scenarios 1a, 1b includes coveralls long pants, long sleeved shirt, socks & shoes, and **gloves** (no respirator), 2a and 2b includes coveralls long pants, long sleeved shirt, socks & shoes, and **gloves** (no respirator). For scenarios 3a and 4a PPE includes coveralls long pants, long sleeved shirt, socks & shoes, and no **gloves** (no respirator).

Engineering Control for all scenarios includes long pants, long sleeved shirt, socks & shoes, closed mixing/loading, closed cab tractor and enclosed cockpit.

5.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

Aggregate risk is estimated by combining dietary (food and water) and residential exposures. There are no registered or proposed residential uses for triallate. Therefore, the aggregate risk is estimated from food and water only.

5.1 Acute Aggregate Risk Estimates

Acute aggregate risk estimates do not exceed HED's level of concern.

Two acute dietary exposure analyses (one for females 13+ and the other for the general population using two different endpoints) using the Dietary Exposure Evaluation Model (DEEM™) were conducted for a refined Tier 3 approach for acute dietary exposure. The DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-91 Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. For the acute dietary analyses, anticipated residues and percent of crop treated data were used. HED's level of concern for acute dietary risk is >100% of the aPAD. Refined acute dietary exposure and risk estimates associated with the supported and proposed uses of triallate **are significantly below (<2% aPAD) HED's level of concern** for all population subgroups. Potential residues in drinking water are not greater than HED's acute DWLOCs.

5.2 Chronic (non-cancer) and Cancer Aggregate Risk Estimates

Chronic (non-cancer) aggregate risk estimates do not exceed HED's level of concern.

A dietary exposure analysis using the Dietary Exposure Evaluation Model (DEEM™) was completed for a refined Tier 3 approach for chronic (non-cancer) dietary exposure. The DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-91 Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. For all dietary analyses, anticipated residues and percent of crop treated data were used. HED's level of concern for chronic (non-cancer) dietary risk is >100% of the cPAD. Refined chronic (non-cancer) dietary exposure and risk estimates associated with the supported and proposed uses of triallate **are significantly below (<1% cPAD) HED's level of concern** for all population subgroups. Potential residues in drinking water are not greater than HED's chronic DWLOCs.

Chronic (cancer) aggregate risk estimates do exceed HED's level of concern.

The Agency generally considers 1×10^{-6} as negligible risk (i.e., less than 1 in 1 million) for cancer. The results of this analysis indicate that the cancer dietary food risk estimate of 7.1×10^{-8} associated with the uses supported through reregistration and the proposed use on sugar beets of triallate is below the Agency's level of concern.

The cancer DWLOC is 0.45 ppb. The Tier II (PRZM-EXAMS) estimated average concentration of triallate + TCPSA in surface water is 0.566 ppb (mean annual with 2" incorporation) and 1.257 ppb (mean annual with no incorporation). Concentrations in ground water are not expected to be higher than 0.21 ppb. **The annual mean estimated concentrations exceed OPP's DWLOCs for triallate +TCPSA in drinking water as a contribution to cancer aggregate exposure.**

Non-targeted surface water monitoring data from the USGS National Water Quality Assessment (NAWQA) program indicate that chronic concentrations of triallate in filtered surface waters from high use triallate areas are substantially lower than PRZM-EXAMS predictions. The maximum time-weighted annual mean concentration of triallate (parent only) in surface water is 0.077 ppb. Surface water data from Canadian monitoring studies on unfiltered surface waters suggest similar trends. There are no surface water monitoring data for TCPSA to assess runoff potential from actual triallate use.

The drinking water exposure assessment, based on monitoring and modeling data, indicate that triallate (parent only) concentrations are below the cancer DWLOC. However, with no monitoring data available for the metabolite, TCPSA, and the surface water EECs of cumulative triallate residues exceeding the cancer DWLOC, HED cannot conclude with reasonable certainty that no harm will result from cancer aggregate exposure to triallate and TCPSA residues.

6.0 ENDOCRINE DISRUPTOR EFFECTS

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of triallate for endocrine effects.

7.0 CUMULATIVE EXPOSURE AND RISK

EPA does not have, at this time, available data to determine whether triallate has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance reassessment, therefore, EPA has not assumed that triallate has a common mechanism of toxicity with other substances.

8.0 DATA NEEDS

8.1 Toxicology

No data gaps.

8.2 Residue Chemistry

Pertinent product chemistry data requirements remain unfulfilled for the Monsanto 94% T/TGAI concerning discussion of formation of impurities, stability, pH, UV/visible absorption, and octanol/water partition coefficient (OPPTS 830.1670, 6313, 7000, 7050, and 7550). Provided that the registrant submits the data required in the attached data summary tables for the 94% T/TGAI, and either certifies that the suppliers of beginning materials and the manufacturing process for the triallate technical product have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, HED has no objections to the reregistration of triallate with respect to product chemistry data requirements.

No additional data are required for wheat straw. Although a tolerance has not been established for wheat forage, adequate data are available for this wheat RAC. Wheat hay has now been included in Table 1 (OPPTS GLN 860.1000) as a significant livestock feed item. Therefore the following are required: Data depicting residues of triallate and its TCPSA metabolite in/on the hay of spring and winter wheat harvested following a single preemergence soil application of representative G and EC formulations at 1.5 lb ai/A. Separate (or side-by-side) field trials should be conducted for each registered formulation. The trials must be conducted in the states of CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY where regional registration is currently permitted. Wheat hay samples should be analyzed within the storage intervals for which residues have been demonstrated to be stable under frozen storage conditions. The registrant will be required to propose tolerances for wheat hay when acceptable data have been submitted and evaluated.

No additional data are required for barley straw. Barley hay has now been included in Table 1 (OPPTS GLN 860.1000) as a significant livestock feed item. The requested wheat hay data may be translated to barley hay since the registered uses of triallate on barley and wheat are identical. The registrant will be required to propose a tolerance for barley hay when acceptable wheat hay data have been received and evaluated.

A barley processing study utilizing exaggerated application rate (or a rate equivalent to the maximum theoretical concentration factor) is required. If the exaggerated field trial should result in non-quantifiable residues of triallate and its TCPSA metabolite in/on the RAC (barley grain), then the harvested RAC samples need not be processed, and tolerances for barley processed commodities will not be required. However, if the exaggerated rate should produce quantifiable residues in/on the RAC, then the harvested RAC samples should be processed into pearled barley, flour, and bran according to method(s) simulating commercial practices. Each processed fraction should be analyzed for triallate residues of concern.

Because triallate residues of concern (triallate and its TCPSA metabolite) were detected in rotational crop commodities, limited field rotational crop studies must be conducted. The limited field trials should be conducted on representative crops of the root and tuber vegetables, leafy vegetables, and small grains at two sites per crop for a total of six trials. The six trials should be conducted on crops which the registrant intends to have as rotational crops on the product labels. Samples should be analyzed for residues of triallate and its TCPSA metabolite. If these limited field trials indicate that quantifiable triallate residues of concern will occur, then extensive field rotational crop trials and rotational crop tolerances will be required. The registrant should consult OPPTS GLN 860.1900 (Field Accumulation in Rotational Crops) for additional guidance concerning this requirement.

The need for rotational crop tolerances and restrictions will be determined following submission of the required field rotational crop studies.

8.3 Occupational/Residential

No data gaps.